EXHIBIT K

THE GOVERNMENT OF PUERTO RICO
COURT OF FIRST INSTANCE
SUPERIOR COURT, SAN JUAN PART

THE GOVERNMENT OF PUERTO RICO Plaintiff, v. **TEVA PHARMACEUTICAL INDUSTRIES, LTD; TEVA PHARMACEUTICALS USA, INC.; CEPHALON, INC.; ALLERGAN PLC F/K/A ACTAVIS PLC F/K/A ALLERGAN, INC.; ALLERGAN FINANCE, LLC, F/K/A/ ACTAVIS, INC., F/K/A WATSON PHARMACEUTICALS, INC.; ALLERGAN SALES, LLC; ALLERGAN USA, INC.; WATSON LABORATORIES, INC.; ACTAVIS PHARMA, INC. F/K/A WATSON PHARMA, INC.; ACTAVIS SOUTH ATLANTIC LLC; ACTAVIS ELIZABETH LLC; ACTAVIS MID ATLANTIC LLC; ACTAVIS TOTOWA LLC; ACTAVIS LLC; ACTAVIS KADIAN LLC; ACTAVIS LABORATORIES UT, INC., F/K/A WATSON LABORATORIES, INC.-SALT LAKE CITY; ACTAVIS LABORATORIES FL, INC., F/K/A WATSON LABORATORIES, INC.-FLORIDA, and TEVA PUERTO RICO LLC, F/K/A WARNER CHILCOTT COMPANY, LLC** Defendants.	CASE NO.

COMPLAINT

I. PRELIMINARY STATEMENT

1. Plaintiff the Government of Puerto Rico brings this action to redress the unfettered and unlawful sale of opioids into Puerto Rico by Teva Pharmaceutical Industries, Ltd., Teva Pharmaceuticals USA, Inc., Cephalon, Inc., ("Teva") Allergan Finance, LLC f/k/a Actavis, Inc., f/k/a Watson Pharmaceuticals, Inc., Allergan plc, Allergan Sales, LLC; Allergan USA, Inc.; ("Allergan"); Watson Laboratories, Inc.; Actavis Pharma, Inc., f/k/a/ Watson Pharma, Inc.; Actavis South Atlantic LLC; Actavis Elizabeth LLC; Actavis Mid Atlantic LLC; Actavis Totowa LLC; Actavis LLC; Actavis Kadian LLC; Actavis Laboratories UT, Inc. f/k/a Watson Laboratories, Inc.-Salt Lake City; and Actavis Laboratories FL, Inc., f/k/a Watson Laboratories, Inc.-Florida, and Teva Puerto Rico LLC f/k/a Warner Chilcott Company, LLC (the "Former Actavis Entities") (collectively "Defendants").

2. From 2006 to 2014, the years for which ARCOS data is available,[1,2] the Defendants were responsible for over **32 million** dosage units shipped into Puerto Rico. Specifically, Teva was responsible for 4,444,560 dosage units of opioids shipped into Puerto Rico; the Former Actavis Entities were responsible for 27,761,665 dosage units of opioids shipped into Puerto Rico; and Allergan was responsible for 30,900 dosage units of opioids shipped into Puerto Rico during this time span.

3. Prescription opioids are narcotics. They are derived from, and possess properties similar

[1] The federal Drug Enforcement Administration ("DEA") maintains a system of records, known as the "Automated Records and Consolidated Orders System/Diversion Analysis and Detection System (ARCOS/DADS)," to which all distributors and manufacturers of controlled substances are required to report each transaction in these drugs. These companies have typically opposed disclosure of the information contained in the system, often referred to as "ARCOS data," arguing that it belongs to them as trade secrets. Data for the years 2006 to 2014, however, has been disclosed to the Government of Puerto Rico and made public through other litigation against Defendants and others.

[2] The opioid purchases disclosed in the ARCOS data serve as an effective proxy for the opioids sold by Defendants, who have no incentive to purchase drugs they do not plan to sell.

to, opium and heroin, and they are regulated as controlled substances. While opioids can dampen the perception of pain, they also can create a euphoric high and are highly addictive. At higher doses, they can slow the user's breathing, causing potentially fatal respiratory depression. Because the medical community recognized these dangers, they originally used opioids cautiously and sparingly, typically only for short-term acute pain or for palliative (end-of-life) care. Consequently, the prescribing of opioids was sharply constrained.

4. In the mid-1990s, however, pharmaceutical companies, including Purdue Pharma, Inc. ("Purdue"), which Puerto Rico sued on March 27, 2018, Janssen Pharmaceuticals, Inc., and Johnson & Johnson, ("Janssen") which Puerto Rico sued on September 12, 2018, and Mallinckrodt, which Puerto Rico sued on December 20, 2019, aggressively and deceptively marketed opioids for common chronic conditions like back pain, migraines, and arthritis. By the mid-2000s, chronic opioid therapy—the prescribing of opioids long-term to treat chronic pain—became widespread and the use of opioids skyrocketed.[3] According to the Center for Disease Control ("CDC"), opioid prescriptions, as measured by number of prescriptions and morphine milligram equivalents ("MMEs") per person, tripled from 1999 to 2015. In 2015, on an average day, more than 650,000 opioid prescriptions were dispensed in the United States.

5. Taking advantage of this mass market, Defendants flooded many communities with opioids, without conducting the due diligence required by law to prevent the diversion of opioids to an illicit market in these drugs that predictably developed, and that Defendants helped create, expand, and maintain.

6. Defendants have a duty under Puerto Rico law, as well as federal law, to maintain effective controls to prevent diversion and to monitor, report, and reject suspicious orders of controlled

[3] In this Complaint, "chronic pain" means non-cancer pain lasting three months or longer.

substances. Such orders include, for example, orders of opioids that exceed reasonable volume, are of an unusual frequency or pattern, or that raise other red flags.

7. Data available to Defendants, as well as their own observations, would have, or should have, put them on notice of potential diversion. Yet, upon information and belief, Defendants consistently failed to guard against diversion of the opioids they sold, and even put policies in place that undermined their obligations, deepening the crisis of opioid abuse, addiction, and death in Puerto Rico.

8. Despite the multi-million volume of opioids sold by Defendants, upon information and belief, Defendants did not report **any** suspicious orders between 2007 and 2014.

9. The opioid crisis has become a full-blown national epidemic. Nationally, the number of deaths due to drug overdoses rose from 16,849 in 1999 to 63,632 in 2016. In 2017, there were 70,237, opioid-related deaths, a 9.6% increase from 2016. More recently, from May 2019 to May 2020, over 81,000 drug overdose deaths occurred in the United States.[4] Sadly, in 2020, the COVID-19 pandemic only further exacerbated the opioid crisis, and preliminary data shows that in 2020, overdose deaths related to opioids likely topped over 90,000 deaths in the year alone.[5]

10. Puerto Rico has not been spared from this deadly trend. From January 1, 2007, until the end of 2015, Puerto Rico experienced 1,661 overdose deaths from controlled substances, including alcohol. Additionally, in 2000 there were 436 overdose deaths related to controlled substances, including alcohol, in 2001 there were 417 deaths, in 2002 there were 383 deaths, in 2003 there were 355 deaths, in 2005 there were 296 deaths, and in 2006 there were 332 deaths. Further, according to surveys conducted on those who suffer from addiction in Puerto Rico, the most frequently reported drug used – at 46% of those surveyed – was opioid analgesics.

[4] https://www.cdc.gov/media/releases/2020/p1218-overdose-deaths-covid-19.html
[5] https://www.washingtonpost.com/politics/2021/04/07/health-202-overdose-deaths-may-have-topped-90000-2020/

11. Beyond overdoses, Puerto Rico hospitals have struggled to deal with other effects of the opioid epidemic. "Mi Salud," the Medicaid-based public health insurance program in Puerto Rico, which covers approximately 45% of Puerto Rico's residents, reported 1,314 claims in 2016 for non-fatal opioid-related emergency room visits. Mi Salud spent nearly $4 million on opioid-related claims in 2012, and this number increased to over $6 million in 2013. In 2014, this number increased again—to over $9 million. Hospitals in Puerto Rico have incurred financial costs due to the opioid crisis because hospitals have increased dispensing medications for patients seeking opioids and opioid-related effects, such as overdoses that health care plans do not cover.

12. Law enforcement, likewise, has both shouldered and witnessed the costs of opioid abuse and diversion. In 2016, there were nearly 550 arrests in Puerto Rico for opioid possession and nearly 15,000 pills gathered as evidence from arrests. Further, in 2016, the Puerto Rico Police Department reported finding an additional 10,034 opioid pills unrelated to an arrest, clear evidence that opioids are being diverted within the Island.

13. Teens and adolescents in Puerto Rico have been introduced to prescription opioids through their own prescriptions and through prescription drugs found in medicine cabinets in their homes. In either case, their misuse of opioids can be traced to prescription opioids that became available in quantities and doses that were unheard of before Defendants flooded Puerto Rico with opioids. According to a survey conducted at schools across Puerto Rico, as many as 8.6% of children ages 12-17 are using prescription pills, including opioids, to get high. The illegal selling of pills is contributing to an underground economy for prescription painkillers that Defendants fostered and sustained, fueling the opioid crisis in Puerto Rico.

14. Even infants have been impacted by opioids due to suffering from neonatal abstinence syndrome ("NAS"). The Puerto Rico insurance program spends an average of $1,000 daily on

each baby who suffers from NAS.

15. Despite the fact that Defendants sold tens of millions of opioid pills, equating to hundreds of millions MMEs, in Puerto Rico, Defendants had an insufficient suspicious order monitoring program.

16. The Secretary of the Department of Justice of Puerto Rico ("Department of Justice") brings this action pursuant to his constitutional and statutory authority, alleging that Defendants have violated, and continue to violate, the Laws of Puerto Rico, including 10 L.P.R.A. §259(a) (prohibiting unfair methods of competition and unfair or deceptive acts or practices in trade or commerce), 31 L.P.R.A. §5141 (damage caused through fault or negligence), 32 L.P.R.A. §2761, 32 L.P.R.A. §3532 (public nuisance), and that Defendants were unjustly enriched. Pursuant to 31 L.P.R.A. §7, in the absence of a statute, the Court "shall decide in accordance with equity."

17. Accordingly, Puerto Rico brings this action to hold Defendants accountable for their conduct and seeks abatement, civil penalties, damages, and any other injunctive and equitable relief within this Court's powers to redress and halt these unlawful practices.

II. PARTIES

18. Plaintiff brings this action, by and through the Secretary of Justice, Domingo Emanuelli, to protect the interests of Puerto Rico and its residents. The Secretary of Justice brings this action pursuant to his constitutional and statutory authority, including the authority granted to him by 10 L.P.R.A. §268(b).

19. Defendant Teva Pharmaceuticals USA, Inc. ("Teva USA") is a Delaware corporation with its principal place of business in Pennsylvania.

20. Defendant Cephalon, Inc. is a Delaware corporation with its principal place of business in Frazer, Pennsylvania.

21. Both Teva USA and Cephalon, Inc. are wholly owned subsidiaries of Defendant Teva Pharmaceutical Industries Ltd ("Teva Ltd."), a company based in Israel. Since Teva Ltd. acquired Cephalon, Inc. in 2011, Cephalon's United States sales and marketing activities have been conducted by Teva USA.

22. The close connection between Teva Ltd. and its U.S. subsidiaries, as well as the blurred distinction between them, is shown in Teva's websites. For example, on Teva USA's website is a page entitled "Teva Pharmaceutical Industries Limited," on a page labelled "intended for US residents only," which includes the following: "Teva improves health in the US every day, every minute, every second. One in every six prescriptions dispensed in the US is a Teva product. Approximately 22 prescriptions in the US are filled by Teva products every second . . . Teva is the world's largest maker of generic pharmaceutical products."[6] Teva Ltd.'s financial reports list Cephalon's and Teva USA's sales as its own, and its year-end report for 2012 attributed a 22% increase in its specialty medicine sales to "the inclusion of a full year of Cephalon's specialty sales . . . ." [7] The United States is the largest of Teva Ltd.'s global markets, and it represents nearly half of its total revenue.[8]

23. Other publicly available information demonstrates Teva Ltd.'s control over Cephalon's operations: For example, immediately after acquiring Cephalon, Teva Ltd. caused Cephalon to

[6] https://www.tevausa.com/Company.aspx
[7] New Yorker; Fact Sheet Teva Pharmaceutical Industries Ltd. Annual Report (Form 20-F) (Feb. 12, 2013) at 62.
[8] *Id*. at 62-64.

increase its product prices up to twenty-five percent.[9] The two companies combined sales forces,[10] product pipelines, and research and development efforts.[11]

24. Teva Ltd., Teva USA, and Cephalon, Inc. are collectively referred to herein as "Teva."

25. Teva manufactures, promotes, sells, and distributes branded opioids Actiq, a fentanyl lollipop, and Fentora, a dissolving fentanyl pill, throughout the United States and Puerto Rico. Actiq and Fentora have been approved by the FDA only for the management of breakthrough cancer pain in patients 16 years of age and older who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain.

26. In 2008, Cephalon pled guilty to a criminal violation of the Federal Food, Drug and Cosmetic Act for its misleading off-label promotion of Actiq and two other drugs and agreed to pay $425 million.

27. Teva also sells generic opioids through the United States and Puerto Rico, including generic opioids previously sold by Allergan plc, whose generics business Teva's parent company acquired in August 2016. Generics sold by Teva include oxymorphone and hydrocodone.

28. Allergan plc (f/k/a Actavis plc, f/k/a Allergan, Inc.) is a public limited company incorporated in Ireland with its principal place of business in Dublin, Ireland, and its administrative headquarters and all executive officers located in Madison, New Jersey. In October 2012, the Actavis Group was acquired by Watson Pharmaceuticals, Inc., and the combined company changed its name to Actavis, Inc. as of January 2013, and then to Actavis plc in October 2013. In

[9] Tracy Staton, *Teva jacks up prices on Cephalon legacy brands* (Dec. 7, 2011),http://www.fiercepharma.com/story/tevajacks-prices-cephalon-legacy-brands/2011-12-07.
[10] *NASDAQ OMX 27th Investor Program Conference Call,* Teva Pharm. Indus. Ltd. (Dec. 6, 2011, 5:15 AM), http://seekingalpha.com/article/315684-teva-pharmaceuticals-management-presents-at-nasdaq-omx-27th-investor-program-transcript?page=4.
[11] *See generally, Teva Pharmaceuticals Industries ' Management Presents at Citi Global Health Care Conference (Transcript)* (Mar. 8, 2012), http://seekingalpha.com/article/419471-teva-pharmaceutical-industries-management-presents-at-citi-global-health-care-conference-transcript.

October 2013, Actavis plc (n/k/a Allergan plc) acquired Warner Chilcott plc pursuant to a transaction agreement dated May 19, 2013. Actavis plc (n/k/a Allergan plc) was established to facilitate the business combination between Actavis, Inc. (n/k/a Allergan Finance, LLC) and Warner Chilcott plc. Following the consummation of the October 1, 2013 acquisition, Actavis, Inc. (n/k/a Allergan Finance, LLC Inc.) and Warner Chilcott plc became wholly-owned subsidiaries of Actavis plc (n/k/a Allergan plc). Pursuant to the transaction, each of Actavis, Inc.'s common shares were converted into one Actavis plc share. Further, Actavis plc (n/k/a Allergan plc) was the "successor issuer" to Actavis, Inc. and Warner Chilcott. Actavis plc acquired Allergan, Inc. in March 2015, and the combined company thereafter changed its name to Allergan plc.

29. The transaction that created Actavis plc converted each share of Actavis Inc.'s Class A common shares into one Actavis plc Ordinary Share.[12] Actavis Inc. and Actavis plc had the same corporate headquarters both before and after the merger; Actavis plc had the same website as Actavis Inc.; and, Actavis plc maintained all of Actavis Inc.'s officers in the same positions.[13] Actavis plc's SEC filings explained that "references throughout to 'we,' 'our,' 'us,' the 'Company' or 'Actavis' refer interchangeably to Watson Pharmaceuticals, Inc., Actavis, Inc., and Actavis plc depending on the date."[14]

30. Defendant Allergan Finance, LLC (f/k/a Actavis, Inc., f/k/a Watson Pharmaceuticals, Inc.) is a limited liability company incorporated in Nevada and headquartered in Madison, New Jersey. Allergan Finance, LLC is a wholly-owned subsidiary of Allergan plc.

[12] *See City of Chicago v. Purdue Pharma L.P., et al*. (N.D. Ill. 2015), No. 14-4361, 2015 WL 2208423, at *7.
[13] *See id*.
[14] *See id.*

31. Defendant Allergan Sales, LLC is incorporated in Delaware and headquartered in Irvine, California. Allergan Sales, LLC is a wholly-owned subsidiary of Allergan plc.

32. Defendant Allergan USA, Inc. is incorporated in Delaware and headquartered in Madison, New Jersey. Allergan USA, Inc. is a wholly-owned subsidiary of Allergan plc.

33. Allergan plc; Allergan Finance, LLC; Allergan Sales, LLC; and Allergan USA, Inc. are collectively "Allergan." Allergan manufactures or has manufactured branded and generic opioids.

34. Defendant Watson Laboratories, Inc. is a Nevada corporation with its principal place of business in Corona, California. Watson Laboratories, Inc. was sold to Teva Pharmaceutical Industries Ltd. as part of Allergan plc's 2016 sale of its generic businesses to Teva. Prior to the sale, Watson Laboratories, Inc. was a direct subsidiary of Actavis, Inc. (n/k/a Allergan Finance, LLC). Watson Laboratories, Inc. was also the ANDA holder of various generic opioids.

35. Defendant Teva Puerto Rico LLC f/k/a Warner Chilcott Company, LLC is a pharmaceutical company located in Fajardo, Puerto Rico. Warner Chilcott Company, LLC, which changed its name to Teva Puerto Rico LLC in 2018, was a subsidiary of Warner Chilcott plc until Warner Chilcott plc became a wholly owned subsidiary of Allergan plc in 2013. Warner Chilcott Company LLC was sold to Teva Pharmaceutical Industries Ltd. as part of Allergan plc's 2016 sale of its generic businesses to Teva.

36. Defendant Actavis Pharma, Inc. (f/k/a Watson Pharma, Inc.) is a Delaware corporation with its principal place of business in New Jersey. Actavis Pharma, Inc. was sold to Teva Pharmaceutical Industries Ltd. as part of Allergan plc's 2016 sale of its generic businesses to Teva.

37. Defendant Actavis South Atlantic LLC is a Delaware limited liability company with its principal place of business in Sunrise, Florida. Actavis South Atlantic LLC was listed

as the ANDA holder for oxymorphone and fentanyl transdermal. Actavis South Atlantic LLC was sold to Teva Pharmaceutical Industries Ltd. as part of Allergan plc's 2016 sale of its generic businesses to Teva.

38. Defendant Actavis Elizabeth LLC is a Delaware limited liability company with its principal place of business in Elizabeth, New Jersey. Actavis Elizabeth LLC was also the holder of ANDAs for the following Schedule II opioid products: oxycodone/acetaminophen; homatropine methylbromide/hydrocodone bitartrate; morphine sulfate capsule; morphine sulfate tablet; oxycodone/hydrochloride tablet; oxycodone/ibuprofen; and oxymorphone tablet. Actavis Elizabeth LLC was sold to Teva Pharmaceutical Industries Ltd. as part of Allergan plc's 2016 sale of its generic businesses to Teva.

39. Defendant Actavis Mid Atlantic LLC is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey. Actavis Mid Atlantic LLC has held the ANDA for homatropine methylbromide/hydrocodone bitartrate. Actavis Mid Atlantic LLC was sold to Teva Pharmaceutical Industries Ltd. as part of Allergan plc's 2016 sale of its generic businesses to Teva.

40. Defendant Actavis Totowa LLC is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey. Actavis Totowa LLC has held the ANDAs for the following Schedule II opioid products: oxycodone/acetaminophen; homatropine methylbromide; oxycodone/hydrochloride.

41. Defendant Actavis LLC is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey. Defendants Actavis South Atlantic LLC, Actavis Elizabeth LLC, Actavis Mid Atlantic LLC, and Actavis Totowa LLC were all direct

subsidiaries of Actavis LLC, which was an indirect subsidiary of defendant Watson Laboratories, Inc. Watson Laboratories, Inc., in turn, was a direct subsidiary of Actavis, Inc. (n/k/a Allergan Finance, LLC). Actavis LLC was sold to Teva Pharmaceutical Industries Ltd. as part of Allergan plc's 2016 sale of its generic businesses to Teva.

42. Defendant Actavis Kadian LLC is a Delaware limited liability company with its principal place of business in Morristown, New Jersey. Actavis Kadian LLC was sold to Teva Pharmaceutical Industries Ltd. as part of Allergan plc's 2016 sale of its generic businesses to Teva.

43. Defendant Actavis Laboratories UT, Inc. (f/k/a Watson Laboratories, Inc.-Salt Lake City) is a Delaware limited liability company with its principal place of business in Salt Lake City, Utah. Actavis Laboratories UT, Inc. was sold to Teva Pharmaceutical Industries Limited as part of Allergan plc's 2016 sale of its generic businesses to Teva. Prior to the sale, Actavis Laboratories UT, Inc. was a direct subsidiary of Actavis, Inc. (n/k/a Allergan Finance, LLC).

44. Defendant Actavis Laboratories FL, Inc. (f/k/a Watson Laboratories, Inc.-Florida) is a Florida limited liability company with its principal place of business in Davie, Florida. Actavis Laboratories FL, Inc. was the ANDA holder of the following Schedule II opioid products: hydrocodone/acetaminophen; hydrocodone/ibuprofen; oxycodone/aspirin; and hydromorphone tablet. Actavis Laboratories FL, Inc. was sold to Teva Pharmaceutical Industries Ltd. as part of Allergan plc's 2016 sale of its generic businesses to Teva. Prior to the sale, Actavis Laboratories FL, Inc. was a direct subsidiary of Andrx Corporation, which was a direct subsidiary of Actavis, Inc. (n/k/a Allergan Finance, LLC). Andrx Corporation was transferred to Teva as part of the 2016 sale.

45. Watson Laboratories, Inc.; Actavis Pharma, Inc. (f/k/a Watson Pharma, Inc.), Actavis South Atlantic LLC, Actavis Elizabeth LLC, Actavis Mid Atlantic LLC, Actavis Totowa LLC, Actavis LLC, Actavis Kadian LLC, Actavis Laboratories UT, Inc. (f/k/a Watson Laboratories, Inc.-Salt Lake City), Actavis Laboratories FL, Inc. (f/k/a Watson Laboratories, Inc.-Florida) and Teva Puerto Rico LLC f/k/a Warner Chilcott Company, LLC are together the "Former Actavis Entities." The Former Actavis Entities, with Cephalon, Teva USA, and Teva Ltd. are "Teva."

46. Each of these defendants and entities in Paragraphs 33-46 currently is or was previously owned by Allergan plc, which uses them to manufacture, market, and sell its drugs in the United States. Collectively, these defendants and entities, and their DEA registrant subsidiaries and affiliates that manufacture, promote, distribute, and sell prescription opioids, are referred to as "Allergan."

47. Allergan manufactures or has manufactured branded and generic opioids, including but not limited to generic versions of Kadian, Duragesic, and Opana in the United States.

48. Teva and Allergan are at times referred to collectively herein as "Defendants."

III. FACTUAL ALLEGATIONS

(A) DEFENDANTS FAILED TO PUT IN PLACE PROPER SUSPICIOUS ORDER MONITORING PROCEDURES

49. Until the mid-1990s, opioids were widely thought to be too addictive for use for chronic pain conditions, which would require long-term use of the drugs at increasingly high doses. By the mid-2000s, the medical community had abandoned its prior caution, and opioids were entrenched as a supposedly appropriate—and often the first—treatment for chronic pain conditions. This created both a vastly and dangerously larger market for opioids in Puerto Rico and a lucrative opportunity for Defendants, who compounded this harm by failing to implement

effective controls against diversion and by supplying opioids they knew or should have known were being diverted. Defendants' failure to investigate, report, and terminate orders that they knew or should have known were suspicious breached their statutory duties.

50. Further, publicly available information indicates that Defendants ignored red flags of suspicious orders. This information, along with the information known only to Defendants and their customers with whom they entered into charge-back arrangements, would have alerted them to potentially suspicious orders of opioids in and affecting Puerto Rico.

51. Defendants facilitated the supply of far more opioids than could have been justified by a legitimate market. Their failure to maintain effective controls to prevent diversion, and to investigate, report, and take steps to halt orders that they knew or should have known were suspicious, breached their statutory duties and imposed significant costs upon Puerto Rico to address and prevent the worsening opioid epidemic they caused.

52. Multiple sources impose duties on Defendants to monitor, report and refuse to fill suspicious orders of controlled substances.

53. First, by failing to exercise due diligence to refrain from filling orders that they knew or should have realized were likely being diverted for illicit uses, and by failing to report such orders, Defendants breached their duty to exercise reasonable care in selling controlled, narcotic substances and, as a result, both created and failed to prevent a foreseeable risk of harm to Puerto Rico.

54. Second, Defendants assumed a duty, when speaking publicly about opioids and their efforts and commitment to prevent diversion of prescription opioids, to speak accurately and truthfully. Defendants made statements to the media, regulators, and the public at large claiming to take all reasonable precautions to prevent drug diversion. For example, Allergan publicly touted its

purportedly state-of-the-art Suspicious Order Monitoring ("SOM") systems and processes, and professed its commitment to legal compliance and combatting diversion as evidence of its corporate responsibility.[15]

55. Third, as manufacturers, Defendants violated their obligations under 10 L.P.R.A. § 259, which forbids "unfair methods of competition, and unfair or deceptive acts or practices in trade or commerce." By violating Puerto Rico's Controlled Substances Act ("PRCSA"), 24 L.P.R.A. § 2101, *et seq.*, and the federal Controlled Substances Act ("CSA"), 21 U.S.C. § 801 *et seq.*, Defendants placed themselves at an advantage over their competitors because they failed to maintain effective controls against diversion and dispensed suspicious orders in order to boost their own profits.

56. Defendants also breached the reasonable standard of care required by the PRCSA, 24 L.P.R.A. § 2101, *et seq.*

57. The PRCSA requires that registrants of controlled substances, including Defendants, be registered by the Secretary of Health in order to manufacture and distribute controlled substances in Puerto Rico. 24 L.P.R.A. § 2302. The PRCSA also requires that such registration or licensure be consistent with the public interest, which, in turn, requires that manufacturers and distributors "maintain[] an effective control against the diversion of particular controlled substances and any controlled substance in Schedule I or II . . ." 24 L.P.R.A. § 2303(b)(1).

58. It is well-settled that effective controls against the diversion of controlled substances require manufacturers and distributors to detect, report, and halt suspicious orders. For example, the CSA, 21 U.S.C. § 801 *et seq.* and its implementing regulations impose a duty on registrants (entities, like Defendants, licensed to manufacture and distribute controlled substances) to monitor,

[15] https://www.allergan.com/-/media/allergan/documents/us/Investors/Report-to-the-Stockholders-of-Allergan-Form-the-Board-of-Directors-Board-Report.pdf

detect, report, investigate, and refuse to ship suspicious orders. Specifically, the CSA requires registrants of Schedule II substances like opioids to: (a) limit sales within a quota set by the DEA for the overall production of Schedule II substances; (b) register to distribute opioids; (c) maintain effective controls against diversion of the controlled substances that they distribute; and (d) design and operate a system to identify suspicious orders of controlled substances, halt such unlawful sales, and report them to the DEA. *See* 21 U.S.C. § 823; 21 C.F.R. § 1301.74.[16]

59. The CSA and its implementing regulations, and the PRCSA created a "closed system" of distribution; every entity that handles controlled substances is required to meet specific record-keeping and distribution standards. As the Congressional Record reflects, "Such a closed system should significantly reduce the widespread diversion of these drugs out of legitimate channels into the illicit market, while at the same time providing the legitimate drug industry with a unified approach to narcotic and dangerous drug control." 970 U.S.C.C.A.N. 4566. In enacting the CSA, "Congress was particularly concerned with the diversion of drugs from legitimate channels. It was aware that registrants, who have the greatest access to controlled substances and therefore the greatest opportunity for diversion, were responsible for a large part of the illegal drug traffic." *United States v. Moore*, 423 U.S. 122, 135 (1975).

60. The CSA requires manufacturers of Schedule II substances including opioids to: (a) register; (b) maintain effective controls against diversion of the controlled substances that they manufacture or distribute; and (c) design and operate a system to identify suspicious orders of controlled substances, halt such unlawful sales, and report them to the DEA.

[16] *See also* Letter from Joseph T. Rannazzisi, Deputy Assistant Adm'r, Off. of Diversion Control, Drug Enf't Admin., U.S. Dep't of Justice, to Cardinal Health (Sept. 27, 2006), filed in *Cardinal Health, Inc. Inc. v. Holder*, No. 1:12-cv-00185-RBW (D.D.C. Feb. 10, 2012), ECF No. 14-51 (hereinafter, "2006 Rannazzisi Letter"); Letter from Joseph T. Rannazzisi, Deputy Assistant Adm'r, Off. of Diversion Control, Drug Enf't Admin., U.S. Dep't of Justice, to Cardinal Health (Dec. 27, 2007), filed in *Cardinal Health, Inc. v. Holder,* No. 1:12-cv-00185-RBW (D.D.C. Feb. 10, 2012), ECF No. 14-8 (hereinafter, "2007 Rannazzisi Letter").

61. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency. 21 C.F.R. § 1301.74(b). These criteria are not exclusive; any one of them can trigger the duty to report and stop shipment, and other factors not listed in the regulations also may point to suspicious orders. A volume of orders of a controlled substance disproportionate to the population or historic use in an area, for example, may provide reason for suspicion. In addition, orders skewed toward high-dose pills or drugs valued for abuse should alert manufacturers to potential diversion.

62. A manufacturer can only fill, and avoid reporting, suspicious orders of opioids after a diligent investigation has allayed the reason for its suspicion. Of course, due diligence efforts must be thorough: "the investigation must dispel all red flags indicative that a customer is engaged in diversion to render the order non-suspicious and exempt it from the requirement that the distributor 'inform' the [DEA] about the order. Put another way, if, even after investigating the order, there is any remaining basis to suspect that a customer is engaged in diversion, the order must be deemed suspicious and the Agency must be informed."[17] This due diligence requirement extends, in the case of manufacturers, to an obligation to "know your customers' customer." It is not enough to ship opioids to wholesalers and distributors and trust them to do the right thing.

63. The DEA has testified in *In Re: National Opiate Litigation*, MDL 2804 ("MDL") that:

a. DEA registrants are required to block all suspicious orders of prescription opioids.[18]
b. Shipping a suspicious order is a per se violation of federal law.[19]
c. If a wholesale distributor blocks a suspicious order, they should terminate all future sales to that same customer until they can rule out that diversion is occurring.[20]

[17] *Masters Pharmaceuticals, Inc.*, Decision and Order, 80 Fed. Reg. 55418-01 at *55477 (DEA Sept. 15, 2015).
[18] *See* Prevoznik Dep. Vol II, 770:6 to 771:20, April 18, 2019 (DEA 30(b)(6) designee).
[19] *Id.* at 632:7 to 633:2.
[20] *Id.* at 628:24 to 629:15.

d. After-the-fact reporting of suspicious orders has never been in compliance with federal law.[21]

64. In sum, the law imposes on Defendants, due to the position of special trust and responsibility afforded by their license to manufacture and profit from prescription opioids, a duty to help prevent diversion.[22] Defendants may not ignore red flags of illegal conduct and must use the information available to them to identify and report potential diversion. That would include reviewing their own data, relying on their observations of prescribers, pharmacies, and customers, and following up on reports or concerns of potential diversion.

65. As laid out below, Defendants systemically failed to comply with the law. Their shipments of orders destined for unlawful channels, and their failure to report and halt potential diversion, perpetuated the opioid epidemic in Puerto Rico and imposed, and continue to impose, substantial costs upon the Government. Defendants have a duty, and are expected, to be vigilant in deciding whether a prospective customer can be trusted to deliver opioids only for lawful purposes. Defendants breached these duties by failing to: (a) maintain effective controls to prevent diversion; (b) report suspicious orders; and (c) halt shipments of opioids in quantities they knew or should have known could not be justified and were indicative of an oversupply of opioids.

[21] *Id.* at 673:7 to 674:13, 679:20 to 680:8.

[22] The existence of this duty at all relevant times is confirmed by the MDL's grant of partial summary judgment to the "Track One" bellwether plaintiffs. There, the MDL Court held, that defendants, had, and have, an obligation under the federal Controlled Substances Act ("CSA") to identify and report suspicious orders, and not to ship suspicious orders unless due diligence reasonably dispels the suspicion. Grounding its holding in uniform precedent, as well as the plain language of the statute and its implementing regulations, the Court described itself as "hard-pressed to think of a more basic requirement than not to ship a dubious order bearing indicia that the drugs could be diverted to illegal channels." *See In re: National Prescription Opiate Litig*., Case No. 1:17-MD-2804 Doc. 2483 (N.D. Ohio Aug. 19, 2019). That was the only summary judgment motion granted by the MDL Court, which declined both defendants' and plaintiffs' motions for summary judgment on issues of fact related to their compliance (among others filed by defendants).

i. Defendants Were Aware of Their Obligations.

66. The DEA sent a letter to Defendants on December 27, 2007, reminding them that as registered manufacturers and distributors of controlled substances, they share, and must each abide by, statutory and regulatory duties to "maintain effective controls against diversion" and "design and operate a system to disclose to the registrant suspicious orders of controlled substances." The DEA's December 27, 2007 letter reiterated the obligation to detect, report, and not fill suspicious orders and provided detailed guidance on what constitutes a suspicious order and how to report (e.g., by specifically identifying an order as suspicious, not merely transmitting data to the DEA). The letter referenced the Revocation of Registration issued in *Southwood Pharmaceuticals, Inc.*, 72 Fed. Reg. 36,487-01 (July 3, 2007), which discusses the obligation to report suspicious orders and to have "some criteria to use when determining whether an order is suspicious."

67. In addition, the letter made clear that "rely[ing] on rigid formulas to define whether an order is suspicious may be failing to detect suspicious orders. The letter noted:

> For example, a system that identifies orders as suspicious only if the total amount of a controlled substance ordered during one month exceeds the amount ordered the previous month by a certain percentage or more is insufficient. This system fails to identify orders placed by a pharmacy if the pharmacy placed unusually large orders from the beginning of its relationship with the distributors. Also, this system would not identify orders as suspicious if the order were solely for one highly abused controlled substance if the orders never grew substantially. Nevertheless, ordering one highly abused controlled substance and little or nothing else deviated from the normal pattern of what pharmacies generally order.

68. Defendants were aware of their obligations to maintain effective controls to prevent diversion and to identify, report, and reject, suspicious orders.

ii. Defendants Kept Careful Track of Prescribing Data and Knew About Suspicious Orders and Prescribers but Used the Information for Marketing Instead of Legal Compliance.

69. Defendants funneled far more opioids into communities across the United States, including Puerto Rico, than could have been expected to serve legitimate medical uses, and ignored red flags of suspicious orders.

70. Defendants were in possession of information that they could have used to identify potentially suspicious orders of opioids. Specifically, at all relevant times, Defendants were in possession of national, regional, state, and local prescriber- and patient-level data and information that allowed them to track prescribing patterns over time.

71. This information includes the following facts:

a. Manufacturers have access to detailed data on the sale and distribution of opioids, which can be broken down by zip code, prescriber, and pharmacy, and includes the volume of opioids and dose;
b. Defendants make use of that data to target their marketing and, for that purpose, regularly monitor the activity of doctors and pharmacies;
c. Defendants regularly visit pharmacies and doctors to promote their products, which allows them to observe red flags of diversion; and
d. Defendants purchased chargeback data (in return for discounts) that allowed them to monitor the combined flow of opioids into a pharmacy or geographic area.

72. Manufacturers' access to data that showed where their opioids were going permitted—and obligated—them to identify and prevent diversion. The DEA has confirmed that manufacturers have an obligation to use available chargeback and prescribing data for suspicious order monitoring and as part of effective controls to prevent diversion. Upon information and belief, Defendants possessed chargeback data and could have used it to enable their compliance departments to see that many pharmacies and pain clinics were purchasing opioids from multiple

distributors, a red flag for diversion since it may indicate an intent to avoid detection or limits placed by individual distributors.

73. In addition to chargeback data, Defendants, upon information and belief, also had detailed information from data vendors or other sources. Pharmaceutical companies are the primary customers for the prescribing data sold by these vendors. And, as a routine practice, "[p]harmaceutical companies monitor the return on investment of detailing - and all promotional efforts - by prescription tracking."

74. The data vendors manufacturers obtain this information from include but are not limited to: IMS Health, QuintilesIMS, IQVIA, Pharmaceutical Data Services, Source Healthcare Analytics, NDS Health Information Services, Verispan, Quintiles, SDI Health, ArcLight, Scriptline, Wolters Kluwer, and/or PRA Health Science, and all of their predecessors or successors in interest (the "Data Vendors"). One product sold by IQVIA (formerly IMS) called "Xponent," provided Defendants with information on every opioid prescription filled, tracking the doctor who wrote the prescription and the drug prescribed. Defendants purchased this information from IQVIA in order to assess their own sales efforts. They could track precisely which doctors were prescribing their drugs and tailor their marketing efforts accordingly. IQVIA data was the lynchpin of the Defendants' marketing efforts and, in particular, of the compensation scheme for their sales representatives. Without the detail in the IQVIA data, the Defendants would not have been able to tell which sales representatives were most effective at their jobs, because they would not have known which doctors were writing the prescriptions reflected in their sales.

75. The data provided by these vendors allowed Defendants to track prescribing trends and assess their competition in the market. Defendants could, and did, use the data to view, analyze, compute, and track their competitors' sales, and to compare and analyze market share information.

IQVIA/IMS Health provided Defendants with reports detailing prescriber behavior and the number of prescriptions written between competing products.[23]

76. This data also could have been used by Defendants to track and identify instances of overprescribing, to identify pill mills, and to identify suspicious orders. In fact, one of the Data Vendors' experts testified that the Data Vendors' information could be used to track, identify, report and halt suspicious orders of controlled substances.[24] Defendants used this valuable information for marketing and sales purposes only, however, and did not incorporate it into their suspicious order monitoring programs.

77. Defendants also have specialized and detailed knowledge of the potential suspicious prescribing and dispensing of opioids through their regular visits to doctors' offices and pharmacies. Their extensive boots-on-the-ground presence through their sales forces allows Defendants to observe signs of suspicious prescribing and dispensing.

78. Instead of encouraging them to report potential diversion, however, Defendants' sales incentives rewarded sales representatives who had pill mills within their territories, enticing those representatives to look the other way even when their in-person visits to such clinics should have raised red flags. Defendants' obligation to report suspicious prescribing ran head-on into their marketing strategy. Defendants routinely identified doctors who were their most prolific prescribers, not to report them, but to market to them. It would make little sense to focus on marketing to doctors who may be engaged in improper prescribing only to report them to law enforcement, just as it made little sense to Defendants to report those doctors who drove their sales.

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[23] Paul Kallukaran & Jerry Kagan, *Data Mining at IMS HEALTH: How We Turned a Mountain of Data into a Few Information-Rich Molehills,* http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.198.349&rep=repl&type=pdf, Figure 2 at p.3.

[24] *See Sorrell v. IMS Health,* expert Eugene "Mick" Kolassa testified, on behalf of the Data Vendor, that "a firm that sells narcotic analgesics was able to use prescriber-identifiable information to identify physicians that seemed to be prescribing an inordinately high number of prescriptions for their product." *Id.; see also* Joint Appendix in *Sorrell v. IMS Health,* No. 10-779, 2011 WL 687134, at *204 (Feb. 22, 2011).

iii. Defendants Failed to Monitor the Wholesalers They Used to Supply Their Opioids.

79. Defendants ignored not only their own systemic failures and the suspicious orders into Puerto Rico that they were legally obligated to report and halt, but also that they were relying on large distributors which had systemic failings of their own and lacked the systems to properly guard against diversion.

80. Defendants had a duty to know their direct customers, including the distributors that bought and shipped their drugs in Puerto Rico and across the country. This included an obligation to assess their distributors to ensure they were compliant with applicable law. Any reasonable diligence would have revealed not only glaring, facial deficiencies in distributors' compliance systems, but DEA enforcement actions against these distributors for their noncompliance with the CSA.

81. In May 2014, the United States Department of Justice reported that the DEA had issued final decisions in 178 registrant actions between 2008 and 2012. These included a number of actions against large wholesalers such as AmerisourceBergen Drug Corporation, Cardinal Health Inc., and McKesson Corporation, which the Government sued on June 6, 2018, and which Defendants relied on as their distributors. Certain of these actions evidenced systemic failures that would have impacted Defendants' sales of opioids into Puerto Rico.

82. For example, pursuant to an Administrative Memorandum of Agreement entered into between McKesson and the DEA in January 2017, McKesson admitted that at various times during the period from January 1, 2009 through the effective date of the Agreement (January 17, 2017) it "did not identify or report to [the] DEA certain orders placed by certain pharmacies which should have been detected by McKesson as suspicious based on the guidance contained in the DEA

Letters."[25] McKesson admitted that during this time period it "failed to maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific and industrial channels by sales to certain of its customers in violation of the CSA and the CSA's implementing regulations, 21 C.F.R. Part 1300 *et seq.*," at multiple McKesson distribution centers. As additional examples:

a. On May 2, 2008, McKesson Corporation entered into an Administrative Memorandum of Agreement after the DEA alleged that McKesson failed to maintain effective controls and failed to report suspicious orders or thefts. To resolve these allegations, McKesson paid a $13.25 million civil penalty. The MOU provided that McKesson would "maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform DEA of suspicious orders required by 21 C.F.R. § 1301.74(b), and follow the procedures established by its Controlled Substance Monitoring Program."

b. On April 24, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the AmerisourceBergen Orlando, Florida distribution center alleging failure to maintain effective controls against diversion of controlled substances. On June 22, 2007, AmerisourceBergen entered into a settlement that resulted in the suspension of its DEA registration.

c. Reflecting systemic failures across Cardinal's distribution system, on September 30, 2008, Cardinal Health entered into a Settlement and Release Agreement and Administrative Memorandum of Agreement with the DEA related to its Auburn, Lakeland, Florida, Swedesboro, New Jersey, and Stafford, Texas distribution centers. The DEA alleged that Cardinal failed to maintain effective controls, and Cardinal paid $34 million to resolve these charges.

[25] Settlement Agreement and Release between the U.S. and McKesson Corp., at 5 (Jan. 17, 2017) [hereinafter "2017 Settlement Agreement and Release"] ("McKesson acknowledges that, at various times during the Covered Time Period [2009-2017], it did not identify or report to DEA certain orders placed by certain pharmacies, which should have been detected by McKesson as suspicious, in a manner fully consistent with the requirements set forth in the 2008 MOA."), available at https://www.justice.gov/opa/press-release/file/928471/download.

d. On February 2, 2012, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against Cardinal Health's Lakeland, Florida, facility for failure to maintain effective controls against diversion of oxycodone; and

e. On December 23, 2016, Cardinal Health agreed to pay a $44 million fine to the DEA to resolve the civil penalty portion of the administrative action taken against its Lakeland facility.

83. Chain pharmacies which bought and dispensed prescription opioids from Defendants have likewise faced enforcement actions. For example, in September 2012, the DEA issued an immediate suspension order ("ISO") regarding one of Walgreens'[26] three Schedule II distribution centers, finding Walgreens' distribution practices constituted an "imminent danger to the public health and safety" and were "inconsistent with the public interest." The ISO included, among other information, a statement of facts explaining that Walgreens had not "recognized and adequately reformed the systemic shortcomings discussed" in the ISO. CVS faced similar enforcement actions as well; the company has paid fines totaling over $40 million as the result of a series of investigations by the DEA and the United States Department of Justice ("DOJ").

iv. Defendants Worked in Concert to Limit Enforcement.

84. Defendants worked together to achieve their common purpose through trade or other organizations, such as the Healthcare Distribution Alliance ("HDA"). Through these organizations, Defendants lobbied for higher quotas and to weaken DEA enforcement. Although the HDA membership directory is private, the HDA website confirms that Allergan and Teva were members of the HDA.[27]

[26] The Government of Puerto Rico sued Walgreens on December 19, 2019.
[27] Manufacturer Membership, Healthcare Distribution Alliance https://www.hda.org/about/membership/manufacturer.

85. While Defendants have consistently blamed the DEA for their failure to follow the law and their oversupply of opioids, Defendants worked together in and through HDA to limit the authority of law enforcement to rein in illicit or inappropriate distribution. For example, Defendants, acting through the HDA, lobbied for and drafted portions of the Ensuring Patient Access and Effective Drug Enforcement Act of 2016, which raised the standard for the DEA to suspend a registrant.

86. Defendants also worked to ensure that quotas for opioids allowed by the DEA remained artificially high.

v. Specific Defendants' Failures to Prevent Diversion

Allergan

87. Allergan's SOM system included separate systems operated by two of the Former Actavis Entities, Watson Pharmaceuticals, Inc. ("Watson") and Actavis, Inc. ("Actavis"), which Watson bought in 2012-2013, and by Allergan, which the merged companies then bought in 2015. Neither of the two prior companies, nor the merged group, maintained effective controls against diversion.

88. Before the year-end 2012 merger, Actavis produced twelve different generic opioids, including some of the most abused and diverted opioids such as generic OxyContin (Oxycodone I hydrochloride tablet), generic Opana ER (Oxymorphone tablet) and a generic version of Janssen's Duragesic. From November 2000 through October 2012, the company maintained the same rudimentary threshold-based SOM system. Under that system, a Customer Service group printed a report "several times a day" showing any controlled substance order that was "25% over the customer's rolling average" of orders placed over the prior six months. Then "Customer Service [would] review[] (eyeball[]) the suspicious order report throughout the day (when a new report is created)" and "any order that look[ed] unusual [was] investigated and any unusual items [we]re cleared before the order [wa]s released."

89. This 2000-2012 system only flagged orders unusual in size; it did not flag orders unusual in frequency or pattern in real time, as the law required. It did not utilize any downstream customer information available to Actavis, did not differentiate among National Drug Codes ("NDC"s) for drugs with a higher risk of diversion, nor did it automatically stop orders from shipping. And although Actavis mailed reports to the DEA of orders that were identified in the system from 2009-2012, the lack of any analysis of such data and the fact that Actavis shipped the orders notwithstanding its suspicion, made the reports meaningless.

90. Further, although Actavis's marketing group designed a separate program starting in January 2011, that program tracked only "oxycodone IR suspicious orders." The marketing program compared monthly order rates and noted "any individual customer locations that have ordered 50% or greater than their established six-month order average." It was not designed to track DEA regulations, however, and appears to have been abandoned after only three months of trials.

91. Internal documents reflect that in September 2012, Actavis was implementing a statistics-based, more modern SOM system designed by outside consultants from the Buzzeo/Cegedim group to detect "orders of interest" in "[d]irect Customer sales." On October 1, 2012, that system began working alongside Actavis's prior system.

92. Watson's pre-merger SOM system, like the early pre-merger Actavis system, dated to the early 2000's. This system, however, was even more rudimentary. According to a 2001 memo, Watson's inventory system automatically compiled a "12-month average" of customers' various orders and reported potentially suspicious orders to Customer Service personnel (also known as the "Call Center" group). A May 2004 Operational Procedure added a "SOMS multiplier table" to the system which increased the level at which the inventory system would alert a potentially

suspicious order. The multiplier placed a different value for various "classes of trade." Orders from wholesalers, distributors and chain pharmacies were regularly allowed at triple the historical average or more.

93. The program was also understaffed. Between 2009 and 2012, the Watson Call Center/Customer Relations Operation added no new staff to handle the SOMs "validations" even though the number of validations increased substantially. Between 2009 and 2010 alone, the number of "SOMs validations" handled by each "administrator" jumped from 62 "SOMs validations" per month to an average of 180. In 2011, this number reached 280.

94. The Watson system was further flawed in that it affirmatively allowed customers to get around violations by canceling the order or cutting its quantity. Shipping less of an order does not make it less suspicious; it means only that fewer suspicious drugs are shipped. Through 2012, Watson's consistent policy was not to report the order to DEA, but to simply cut or cancel the order instead. Beginning in 2012, Watson added to its requirements, but merely that "[i]f the customer decides to cancel or reduce the quantity, they will need to provide a reason for the reduction or cancellation." Before the merger with Watson, Actavis's internal documents reflect an understanding that "cutting" an order to a volume that places it beneath the threshold is unacceptable. According to its then-CEO, however, Actavis allowed customers to resubmit unjustifiable suspicious orders in smaller amounts so as to fall below their arithmetic suspicious order monitoring threshold, thereby avoiding reporting.

95. After the merger, the combined company reverted to the existing Watson SOM system, where cutting or cancelling suspicious orders without reporting them was not generally prohibited. Watson also allowed orders to be shipped based on an e-mail justification from an employee (including salespeople with a financial incentive to complete the sale).

96. As described above, like the pre-merger Actavis system, the automated portion of Watson's system only looked for orders of unusual size and not for frequency and/or pattern. The rigid formula used did not satisfy DEA requirements to detect and investigate suspicious orders. The automated portion of the system did not utilize any downstream customer information and did not differentiate among NDCs for drugs with a higher risk of diversion. The SOM program was not an effective control against diversion.

97. On September 28, 2011, Watson received an audit report from the outside consulting firm, Buzzeo/Cegedim, regarding its SOM program. The problems were evident from the very first page: "Watson's current approach is based upon thresholds that are somewhat arbitrary and not in conformance to the specific requirements of the regulations." In its findings, Buzzeo/Cegedim noted that Watson's SOM program was based on the "class of trade" grouping and the application of a "multiplier," as discussed above. The report found that an individual order that was deemed in excess of the multiplier by the class of trade would then be "pended" for investigation by Watson staff, and that approximately 10% of "pended" orders were considered "orders of interest" and sent to security/regulatory for further review. Buzzeo/Cegedim found that, nationwide, Watson reported only **one order** to the DEA. In its recommendations, Buzzeo/Cegedim stated that due to the SOM system's inconsistences with the "specific requirements noted in the regulations and with written guidance provided by the DEA to all registrants" Watson should "revisit its entire approach to SOM to fully address the specific regulatory requirements and other guidance documents provided by the DEA, to include evaluating all orders on the basis of size, frequency, and order pattern deviation.

98. The audit also found that certain accounts, such as McKesson and AmerisourceBergen, had "managed inventories" which are pre-set inventory levels. Watson staff could approve orders

by these accounts when inventory was low. Buzzeo/Cegedim described this system as "self-gaming" and pointed out that reduced inventory is an indicator of increased product movement" and "not a justification for increased order size." Buzzeo/Cegedim recommended that Watson reform its SOM program to identify "unexplained changes in order behavior."

99. Finally, Buzzeo/Cegedim discussed Watson's report identified as "EDI 867" which showed who their customers were selling to. Buzzeo/Cegedim recommended that this report be incorporated into the SOM program to [redacted]

100. Watson did not implement the changes Buzzeo/Cegedim recommended to bring its SOM system into compliance with DEA regulations. Its flawed system remained in place and was carried forward into the merged company.

101. In 2015, the merged company, now known as Allergan, announced it was selling all of its generic drugs and various corporate subsidiaries to Teva. It ceased operating even the deficient Watson SOMs program at that time. Now, Allergan outsources its manufacturing, transport and delivery systems, and is no longer a DEA registrant with regard to its branded opioids: Kadian and Norco. It appears Allergan takes the view that it is a "virtual manufacturer" and need not have a suspicious order monitoring system at all. DEA regulations recognize no category of "virtual" manufacturers, and Allergan cannot delegate its duties to prevent diversion. However, responsibility for the SOMs program remained with Allergan Finance, LLC, which was not included in the sale to Teva.

102. Even before 2015, internal documents show that both Watson and Actavis employees recognized that the suspicious order monitoring systems described above were not an effective control against diversion.

103. In February 2009, the Senior Manager of Actavis's Customer Service Department, Nancy Baran, told her boss that the existing Actavis process was inadequate to "prevent shipping excess product" because it was not cumulative and because there were too many orders over the 25% threshold. Baran would later testify in federal multidistrict litigation arising out of the opioid epidemic (the "MDL") that she remembered only one order between 2008 and 2017 that was ever deemed to be suspicious and reported to the DEA. All other orders flagged by the system were shipped.

104. In a 2011 Project status review, Baran would also make clear that "'Cutting' orders to a volume that puts the order under a threshold is not acceptable." The same presentation explains that the "DEA has stated on this topic 'That is like saying a little bit of diversion is okay.'"

105. On September 12, 2012, at the same time Actavis was preparing to implement the recommended Buzzeo/Cegedim SOM system, Actavis had an approximately three-hour meeting with DEA personnel at the DEA's Arlington, Virginia office to discuss opioid diversion. At the meeting, Barbara J. Boockholdt, Chief of the DEA's Regulatory Section, told Actavis that its products were being distributed in Florida in quantities and under circumstances highly suggestive of diversion. Leonard Levin, Staff Coordinator of the DEA Regulatory Section, told Baran that it should have a member of its compliance team visit certain pharmacies in south Florida "get to know their customers, visit distribution sites, visit customers of those distributors, check on customers' suspicious order monitoring systems, review due diligence files, and obtain printouts of pharmacies or practitioners who are receiving Actavis products" among other steps. Upon

information and belief based on industry practices, however, Actavis already had detailed information about its customers, prescribing doctors, and pharmacies. It simply used this information to advance their sales, rather than to prevent diversion.

106. Actavis's Ethics & Compliance Officer, Michael R. Clarke, testified in the MDL that "the tone and the tenor of the meeting" was such that it seemed the DEA was viewing and speaking with the Actavis representatives "as street dealers" rather than "as professionals." "[T]hey described it," Clarke said, "without using these specific words, but in a way that we would just manufacture, put the product out on the street, and not have a care as to where it went" and "described finding or seeing or obtaining product, you know, opioid products that seemed to be diverted relatively easily."

107. In late October 2012, Actavis had a follow-up meeting with two field representatives from the DEA's Newark, New Jersey office where, according to Clarke, DEA requested a reduction of approximately 30%-40% in Actavis's manufacturing quota for oxycodone. According to Clarke, Actavis's then CEO, Doug Boothe, rejected the DEA's request.

108. Further, like Nancy Baran at Actavis, Thomas Napoli at Watson made clear – internally – that the system did not comply with the DEA laws and regulations. In November 2008 Napoli wrote a memo stating that:

> It is highly recommended that industry utilize a 'total SOM model.' This model favors a more statistically-based model that dynamically evaluates a variety of order characteristics to determine whether an order should be pending. Characteristics include order size, ordering frequency, ordering patterns and percentage of CS ordered.

His memo continued "[t]his approach is viewed to be more effective and defensible than the traditional approach of just setting a threshold." A 2012 PowerPoint from Napoli's files also describes the feedback from Buzzeo/Cegedim as critical.

109. Other internal Allergan emails show that, according to the employees responsible, the suspicious order monitoring system "d[id] a lousy job." One from February 2009 goes to explain "for example"…"if a customer's monthly usage is 3000 units – they can order 2999 units every day of the month and it would not be caught." That same e-mail states that orders in excess of the threshold "come in all day long" and "[i]t would be crippling"..."[i]f Allergan stopped to question and put on hold every one of these orders." In another internal document, Allergan similarly acknowledged its program as "not consistent with specific requirements within the regulations and guidance."

110. As explained above, Allergan was, and should have been, well aware of its obligations. This is particularly true given that its branded opioid, Norco, was so widely diverted that it had the street name "Watson" – the name of Allergan's predecessor that brought the drug to market – and that the DEA blamed it for a "diversion wave." Further, the association between Allergan's predecessors and diversion was not limited to Watson. Actavis, too, was "frequently associated in social media, online message boards, and markets with inappropriate use and questionable distribution" of oxycodone; and its name was adopted by "performers such as 'DJ Actavis,' and songs such as 'Cream Soda and Actavis's."

111. Tellingly, however, former CEO Boothe testified in the MDL that he believed Actavis's responsibility was only to making certain that orders were received from licensed pharmacies and were within numerical thresholds, and that Actavis had no responsibility (or accountability) for preventing diversion:

> Again, I don't think we had responsibility for, accountability for preventing diversion. We had responsibility and accountability for making certain that the orders that we received were valid from licensed pharmacies and were within our suspicious order monitoring thresholds as it was described earlier then with the Buzzeo model or the more statistical model. So we -- that was our responsibility. Once it goes outside of our chain of custody, we have no capability or responsibility or accountability to -- or at

> least my understanding, I'm not a lawyer, as it relates to diversion. So, once we ship a valid order to a wholesaler or ship a valid order to a distributor or another smaller wholesaler, our chain of custody is finished at that point.

112. Despite these failures, Allergan's Board publicly claimed in 2019 that it "employed a number of controls," including holding and flagging suspicious orders, monitoring large shipments, and evaluation of customer data.[28]

113. Allergan's failure to monitor suspicious orders and maintain effective controls to prevent diversion contributed to the spread of illicit opioids in Puerto Rico, causing Puerto Rico to incur costs to address opioid diversion, misuse, addiction, and overdose, among other consequences.

Teva

114. Teva's internal documents show that as of September 2012, Teva had no written suspicious order monitoring system in place and, until that time, never utilized one. In 2012, Teva hired Ronald Buzzeo and Cegedim to perform a review of Teva's SOM system. The review resulted in a starkly critical September 2012 report which noted the absence of written procedures, Teva's failure to report a single suspicious order, **ever**, and the "rudimentary" nature of Teva's program, such as it was. In that regard, the audit also revealed that Teva's customer due diligence process was limited to checking customers' registration and DEA credit-worthiness. Further, the audit explained Teva's order monitoring system was "not sufficiently sensitive to customer ordering practices to result in any meaningful analysis of customer order practices."

115. Teva ultimately decided not to hire Buzzeo to implement a compliance program, a decision that appears to have been based on its assessment of the costs involved.

116. Ultimately, in January 2014 Teva hired Joe Tomkiewicz, who had recently received two visits at his home by DEA agents who advised him to get a lawyer, to design and operate the

[28] https://www.allergan.com/-/media/allergan/documents/us/Investors/Report-to-the-Stockholders-of-AllerganForm-the-Board-of-Directors-Board-Report.pdf

suspicious order monitoring program for this multi-national corporation.

117. Tomkiewicz later coined the program he designed "DefOps," short for "Defensible Operations," a name he admitted in an MDL deposition was chosen because it "sounded good" and was intended to keep Teva out of trouble with the DEA. In August 2014, nearly two years after the Buzzeo report stated Teva needed to have written procedures in place, the written Standard Operating Procedures ("SOPS") for Teva's system finally were approved.

118. The system developed was fundamentally flawed. Most glaringly, the SOPS maintained the key investigatory role in the hands of Teva's sales department. The sales department would then direct customer service to contact the customer for initial investigation and to gather information, and to send a sales representative to the customer if the response was not satisfactory.

119. Teva recognized the conflicts of interest inherent in this system. Notably, Tomkiewicz developed a 2017 PowerPoint on Teva's suspicious monitoring system which references the sales department under the slide titled "Managing Conflicts."

120. Teva's SOM program also suffered from other glaring deficiencies. Teva Ltd. audited Teva's DEA compliance department in 2015 and prepared a report critical of the department and the SOM program. The report stated that Teva Ltd. investigated 10,000 line orders per month of Schedule II products, 95% of which were automatically released. It found that the company's DEA Department was in "non-compliance with DEA requirements" and was at "High Risk" of DEA regulatory action, and that the SOM program was at "Moderate Risk" for such action. For the SOMs program, the report focused primarily on the fact that suspicious orders were cleared through the decisions of a single person (Tomkiewicz), which exposed the system to the risk of mistaken releases. It also recognized that the program must clear 5,000 pending potentially suspicious line orders per month under pressure from the sales department to clear those orders

quickly so as not to delay their customers' opioid orders. That number likely more than doubled after the 2016 acquisition of generic business from Allergan.[29]

121. Internally, Teva also acknowledged that it was not scrutinizing the distributors it used (or chain pharmacies for that matter) as closely as it would other customers.

122. The inadequacy of Teva's system is confirmed by the fact that even after it implemented a written SOMs policy, it reported and stopped very few suspicious orders. Teva reported its first ever suspicious order to the DEA on February 13, 2013. In total, from 2013 through 2016, nationally, Teva reported only **6** suspicious orders out of 600,000 total line orders (and not all were opioid products).

123. Teva's failure to monitor suspicious orders and maintain effective controls to prevent diversion contributed to the spread of illicit opioids in Puerto Rico, causing the Government to incur costs to address opioid diversion, misuse, addiction, and overdose, among other consequences.

(B) CEPHALON AND TEVA'S MISREPRESENTATION OF THE RESULTS OF CLINICAL STUDIES INFLUENCED REIMBURSEMENT COVERAGE DECISIONS, CAUSING HARM TO PUERTO RICO

i. Abuse and Tolerance Concerns Caused the FDA to Limit Actiq's Approval

124. Fentanyl, the active ingredient in Actiq and Fentora, was first approved by the FDA in 1968, not as a pain treatment but as an anesthetic, administered intravenously to produce unconsciousness for surgery.

125. Its initial approval came with no human study of dependence or addiction risks; only animal studies of tolerance and dependence in dogs, monkeys, guinea pigs, and rats.

[29] This was not the only critical safety-related audit of Cephalon. Notably, Teva Ltd. through its Global Drug Safety and Pharmacovigilance Department also conducted an internal audit of Teva USA's pharmacovigilance system. The audit states "the safety system in Teva U.S. has multiple gaps and the reporting of safety matters to the FDA ... cannot be assured." It further stated: "The safety system in Teva U.S. is largely out of control and the reporting of safety matters to FDA (and by extension other regulatory agencies and business partners) cannot be assured."

126. Intravenous fentanyl was restricted to hospital use, administered by medical professionals, and not self-administered by patients.

127. Even with a narrow indication and a curtailed setting, intravenous fentanyl was misused – medical professionals, aware of its potency, abused it, and clandestine labs created illicit versions with names like "China White."

128. In 1993, the FDA approved a fentanyl lozenge called Oralet. Oralet's use was sharply restricted. Like intravenous fentanyl, Oralet's indication was as an anesthetic before surgery for children and adults, and it could only be administered by specialty-trained personnel in controlled settings like hospitals. There were essentially no Oralet prescriptions filled in retail pharmacies.

129. Because of these restrictions, Oralet was never a commercial success for Anesta Corporation (Anesta), its sponsor. Cephalon acquired Anesta in October 2000.[30]

130. Cephalon ceased marketing Oralet altogether in March 2001 when, in the FDA's words, "it became evident that opioid-naïve children who received it could not tolerate the associated adverse events of nausea and vomiting."

131. After failing with Oralet, Anesta tried to obtain approval for another oral form of fentanyl. In 1998, it applied for FDA approval for Actiq, a rapid-release form of fentanyl.

132. Like Oralet, Actiq was a raspberry-flavored fentanyl lozenge on a stick, but it came in higher doses. And to be more commercially successful, Anesta proposed a broader indication than Oralet's: it would not be a pre-surgery sedative; it would be pain treatment for cancer patients.

133. The proposed new indication, however, was still quite restrictive. Anesta proposed that Actiq be limited to treating only cancer patients with metastatic cancers who were still suffering from "breakthrough pain" despite other opioid treatments.

[30] https://www.deseret.com/2000/10/11/19533349/anesta-merges-with-cephalon

134. A key part of the proposed indication was that cancer patients be opioid-tolerant. Opioid-naïve patients faced too great a risk of respiratory depression from fast-acting fentanyl products like Actiq.

135. Anesta sought approval with minimal long-term data on Actiq's risks and benefits. Its long-term evidence consisted of a single, still-ongoing study from which it presented only partial data.

136. The long-term study examined only seriously-ill cancer patients. It was open-label and not controlled, meaning that it did not compare Actiq to a placebo or alternate pain treatments.

137. In addition, the study consisted of a small sample. At the time of approval, only 10 patients had taken Actiq for eight months or more. The study presented no data on abuse, misuse, or addiction, so it did not evaluate abuse liability.

138. The FDA nevertheless thought Actiq's abuse liability was too great. It worried that those with limited exposure to opioids would start abusing Actiq, those already dependent on opioids would become addicted, and those suffering from addiction would become worse.

139. The FDA concluded that Anesta downplayed Actiq's abuse risk with minimal evidence. Anesta had even cited an infamous 1980 letter in the *New England Journal of Medicine* claiming that addiction was "rare in patients treated with narcotics." Anesta had also claimed that it had not detected abuse in its clinical trials, even though it had not looked for or examined abuse in its trials.

140. Because of these risks, the FDA initially issued a "non-approval action" for Actiq in November 1997, citing accidental use and overdose risks to opioid-naïve patients.

141. Anesta tried again. It proposed a restricted approval under 21 C.F.R. § 314.520, which allows the FDA to approve drugs with restrictions on use and marketing "as are needed to assure safe use of the drug product." Restricted approvals are "special safety programs to mitigate serious

risks." By granting a restricted approval, the FDA acknowledges that it would not otherwise approve a drug because its risks would outweigh its benefits. The FDA had never granted a restricted approval for an opioid product; Actiq would become the first.

142. Anesta put its proposed restrictions into a "risk management plan." One of the plan's key purposes was to ensure "proper patient selection." Proper patient selection included ensuring that Actiq was used "solely" to treat breakthrough pain in opioid tolerant cancer patients. Proper patient selection also included preventing Actiq prescriptions for "acute/postoperative pain," for which Actiq was "specifically contraindicated."

143. Based on Anesta's commitments in the risk management plan, the FDA approved Actiq, "when marketed in accordance with the terms of restricted distribution and use described in the Risk Management Program . . . ."

144. Actiq was limited to patients with metastatic cancers because the assessment of opioids' risks and benefits is different for those patients than for others. For patients with metastatic cancer, the benefits of treating their short-term pain and suffering exceeds the short-term risks of adverse events (side effects) and longer-term risks from opioids. In contrast, Actiq was not approved for treatment of chronic non-cancer pain. Chronic non-cancer pain patients need both short-term and longer-term pain relief. They may take pills for a longer period of time than patients with metastatic cancers, in part, because they may live longer. This makes non-cancer chronic pain patients more subject to long-term risks like addiction, drug dependency, analgesic tolerance to opioids' pain-relieving effects, and hyperalgesia (increased sensitivity to pain).

145. Notwithstanding the drug's extreme potency and related dangers, and the FDA's explicit limitations, Cephalon actively promoted Actiq for chronic non-cancer pain — an unapproved, off-label use. Cephalon marketed Actiq as appropriate for the treatment of various conditions

including back pain, headaches, pain associated with sports-related injuries, and other conditions not associated with cancer for which it was not approved, appropriate, or safe.

ii. Cephalon Misrepresented Tolerance and Abuse Risks in Fentora Studies

146. By 2008, Cephalon had largely moved on from Actiq to its new rapid-release fentanyl product, Fentora.

147. It did so in part because Actiq's exclusivity patent expired in 2006, and a number of new immediate-release fentanyl products were due to enter the market, potentially cutting into Actiq's sales.

148. Cephalon was not caught flat-footed – for years it had been outlining a regulatory approval and marketing strategy for Fentora.

149. The strategy began with Cephalon obtaining FDA approval for Fentora for the same limited indication – cancer pain treatment – for which Actiq had been approved.

150. From the start, Cephalon anticipated that even with this limited indication, doctors would still prescribe Fentora off-label. Cephalon estimated that even with the cancer-pain indication, doctors would still largely prescribe Fentora for off-label uses, mainly for back pain and neuropathic pain. Internal projections in 2004 estimated that less than 10% of providers would prescribe Fentora appropriately for cancer patients.

151. Cephalon's marketing plan for Fentora made off-label use a forgone conclusion: the company would simply target the most frequent Actiq prescribers whom, data showed, were largely prescribing Actiq for inappropriate off-label uses.

152. By using the same types of targeting, even with a new compliance system put in place to comply with lawsuit settlements, the public health result for Fentora would remain the same as for Actiq: massive wrongful prescribing of Fentora to non-cancer patients.

153. Cephalon's own market research studies confirm that its Fentora promotions were not focused on the physicians who treat breakthrough cancer pain. Cephalon commissioned several market research studies to determine whether oncologists provided an "adequate" market potential for Fentora. These studies' central goal was to determine whether oncologists treat breakthrough cancer pain themselves, or whether they refer such patients to general pain specialists. The first study, completed in 2007, reported that 90% of oncologists diagnose and treat breakthrough cancer pain themselves and do not refer their breakthrough cancer pain patients to pain specialists. The second study, completed in 2009, confirmed the results of the 2007 study, this time reporting that 88% of oncologists diagnose and treat breakthrough cancer pain themselves and rarely, if ever, refer those patients to general pain specialists. (One reason that general pain specialists typically do not treat oncological pain is that the presence of pain can, in itself, be an indicator of a change in the patient's underlying condition that should be monitored by the treating oncologist.)

154. Cephalon also continued to use its general pain sales force (which numbered over 110 representatives) to promote Fentora to general pain specialists. Cephalon-set sales quotas for its general pain sales force would be unattainable if they did not deceptively promote Fentora off-label.

155. From 2006 to 2019, Cephalon and Teva would rely upon and cite Fentora clinical trial data to support a variety of claims about Fentora's benefits, efficacy, and risks, including in non-cancer pain. As the companies came under more scrutiny and as the opioid crisis worsened, they relied more and more upon these clinical trials as the source for their risk-benefit claims. Understanding how the Fentora clinical trials proceeded provides context for Fentora's approval by the FDA and shows how these trials became a vehicle for deceptive and misleading claims about Fentora's risks and benefits.

156. For Fentora, Cephalon ran two parallel series of clinical trials from 2004 to 2007. One series studied Fentora in cancer patients. The other studied Fentora in opioid-tolerant chronic pain patients who did not have cancer.

157. Each series included a set of short-term, randomized, controlled clinical trials to show that rapid-release Fentora could treat pain.

158. As with the Actiq studies in the 1990s, each series also included a single long-term, non-controlled, open label clinical trial purporting to examine long-term safety and efficacy. But neither of these long-term clinical trials set out to examine risks to patients of abuse, misuse, or addiction, nor did they direct investigators to look for abuse or misuse.

159. The long-term cancer clinical trial ran from April 2004 to November 2006. It tracked opioid-tolerant patients with metastatic cancers for what was supposed to be 12 months and more.

160. Teva later called this the "Weinstein study" after Dr. Sharon Weinstein, the sole non-Cephalon author on a 2009 publication in the journal *Cancer* describing the clinical trial.

161. The long-term non-cancer clinical trial, called "study 3040," overlapped in time, running from March 2005 to May 2007, tracking patients for 18 months. It had more patients than the cancer clinical trial and the patients were not terminally ill – they mainly suffered from chronic back pain.

162. Both of Cephalon's long-term clinical trials allowed patients a surprising amount of discretion in administering Fentora. Patients were given 100 to 150 tablets at once, which was supposed to be a month's supply, which they took home. Patients could take one tablet for every breakthrough pain episode, no matter how close those episodes were, and if pain relief was inadequate, they could take a second tablet. For most of the time these clinical trials ran, there was no limit on the number of tablets that could be used in a single day.

163. If patients went through their 100 to 150 tablets in less than a month, they could come back early to get more. Given 100 or more pills and few limits, patients began abusing and misusing Fentora. In the cancer clinical trial, patients quickly escalated their doses. For example, more than ten of the 197 long-term patients took more than ten pills per day of the strongest dose of Fentora given, 800 mcg. By way of comparison, Cephalon's product label for Actiq at the time warned patients not to take more than four lozenges per day.

164. Cephalon let this continue for more than two years. Then, finally, Cephalon imposed a global cap on all its clinical trials (including both the cancer and non-cancer trials) limiting patients to eight Fentora tablets per day. In reports on the cancer clinical trial, it claimed this amendment was to "provide clarification" to patients, but in other regulatory filings it more candidly admitted "[t]his change was made due to reports that patients were using up to 11 tablets per day for BTP [breakthrough pain]."

165. Cephalon's marketing materials on the cancer trials never disclosed the cap's true purpose.

166. Cephalon furthermore failed to give direction to its study investigators about how to monitor, treat, or track abuse or misuse. Nor did it give investigators clear instructions about how to handle patients abusing or misusing Fentora, including when to withdraw those patients from the clinical trial or how to classify such patients in trial results. As a result, investigators marked 49 of the 197 cancer patients as withdrawing for reasons listed as "Other." Some of these "Other" patients were misusing or abusing Fentora and other opioids during the clinical trial, including the following:

a. Patient 06003 reported the study drug [Fentora] stolen from her home and she "took excessive amt of study drug and claimed her daughter stole her medication";
b. Patient 11006 took 3 doses of study drug but "forgot to put in diary because she

went to Las Vegas" and repeatedly ran out of medication weeks before her scheduled monthly visits and was given more;

c. Patient 32005 was "lethargic at visit, admitted to using methadone day before since he had run out of both orovescent [Fentora] and Actiq. Pt left diaries for past month on the train."
d. Patient 351004 "wasn't completing diaries correctly and seemed to be overusing study drug," claimed to need more Fentora tablets due to them disappearing down kitchen sink, and claimed other Fentora tablets had been "destroyed";
e. Patient 351006 "was going to ER to get additional opiates";
f. Patient 41001 was "taking more study drug than study allows," "ran out" of pills and reported them missing, and was given "firm talking-to" by the investigator about adherence to medication schedule;
g. Patient 86001 was "[n]ot following directions, not providing diary," "continued to use Actiq despite being counseled not to," and "used study medication does [sic.] (100 tabs) before patients was due for refill."

167. There were also at least two patients who were lost to follow up and did not return large numbers of Fentora tablets: Patient 02006 "was sent a certified letter, but no drug has been returned to date" and was marked "lost to follow up," and Patient 26006 who was "non-compliant with appointments to clinic and return of study drug."

168. In study 3040, the non-cancer clinical trial, which had a greater number of patients, there were also frequent incidents of abuse and misuse: 11 patients overdosed; one patient's husband overdosed; 35 patients reported their Fentora stolen; dozens dropped out without accounting for the 100-plus Fentora tablets they had been given; and five study centers reported Fentora stolen from supposedly secured lockers. Cephalon publicly disclosed similar numbers in a trade publication in January 2011 that it did not broadly disseminate. There it stated that across its non-cancer clinical trials, there were 9 Fentora overdoses, 45 medication theft events, and 79 Fentora over-administration events.

169. Beyond the misuse and abuse of opioids, Cephalon's two long-term clinical trials produced data showing that patients who actually completed the trials needed substantially greater daily doses of Fentora over time.

170. In a March 2008 FDA filing, and in a subsequent April 2011 trade publication, Cephalon discussed and presented data and multiple tables and graphs from its non-cancer studies showing that patients were increasing their average daily dose of Fentora over time.

171. In the FDA filing, Cephalon disclosed that patients whom they tracked over 18 months had a 31% increase in pain episodes per day, from 3.5 to 4.6 episodes/day; took 26% more Fentora tablets per day, from 3.5 to 4.4 tablets/day; and had a 42% increase in their average daily Fentora dosage, from 2,162 mcg/day to 3,088 mcg/day. In the April 2011 publication, Cephalon disclosed that patients' average daily dose of Fentora increased over 18 months from 2,108 mcg/day to 3,131.8 mcg/day.

172. As discussed below, in the years to come, Cephalon rarely disclosed this data other than to regulators and in the single April 2011 publication, which it did not disseminate broadly.

173. But Cephalon had similar data from its cancer clinical trials that it appears to have never disclosed.

174. That cancer clinical trial data showed that the few patients who completed 12 months of Cephalon's long term cancer clinical trial had the same signs of tolerance as their non-cancer counterparts. An analysis of Cephalon's own data shows what they buried: the long-term cancer patients also increased their daily dosages of Fentora over time, just as the non-cancer patients did.

175. This data suggests that over time patients might be growing tolerant to Fentora and other opioids, and, as a result, Fentora might not be retaining its efficacy. This is consistent with other data on fentanyl.

176. For the next decade or more, Cephalon and Teva would misrepresent three key outcomes of these clinical trials.

177. First, they would claim patients showed little sign of developing tolerance to Fentora's pain relieving effects when, in fact, they concealed known data suggesting the opposite.

178. Second, they would also claim cancer patients did not misuse or abuse Fentora.

179. Third, they would claim the clinical trials had examined Fentora's long-term risks and safety, when they had not examined long-term risks of abuse, misuse, or addiction.

180. These misrepresentations were communicated to persons at third party payors responsible for determining formularies, leading to available coverage for Actiq and Fentora in Puerto Rico. For example, Cephalon's Fentora Dossier, describes the Weinstein study as establishing "[t]he safety and tolerability of *FENTORA*" and "study 3040" as establishing that Fentora was "generally well tolerated across dose ranges 100 mcg – 800 mcg." It did not give the reason why patients discontinued or listed abuse as an observed risk factor, in this communication to potential payors. Without formulary coverage for the branded drugs, or the expanded market due to off-label promotion, there would not have been a market for generic versions of Actiq and Fentora, which were themselves, upon information and belief, oversupplied in Puerto Rico and subject to abuse.

(C) By Ignoring Mandatory Obligations To Report Suspicious Orders And Guard Against Diversion, Defendants Fueled The Opioid Epidemic And Significantly Harmed Puerto Rico And Its Residents.

181. Defendants compounded the harms from aggressive marketing that overcame barriers to widespread prescribing of opioids for chronic pain by supplying opioids beyond even what this expanded market could bear, and by turning a blind eye to red flags that they were fueling abuse and diversion of these dangerous drugs.

182. By continuing to fill opioid orders without effective policies in place to guard against

diversion, and by failing to report suspicious orders of opioids and to have in place an effective suspicious order monitoring system, Defendants have enabled an oversupply of opioids and supplied opioids that they knew, or should have known, would be used for other than legitimate medical use, would be abused by patients who had become addicted, or would be diverted to non-patients. Defendants also knew, or should have known, that by failing to report suspicious orders and failing to exercise due diligence not to fill suspicious orders, they would facilitate access to opioids for patients who could no longer access or afford prescription opioids and for addicts struggling with relapse.

183. Rising opioid use and abuse also have negative social and economic consequences beyond overdoses, and opioid abuse and misuse. According to an analysis by a Princeton University economist, approximately one out of every three working-age men who are not in the labor force take daily prescription pain medication. The same research finds that opioid prescribing alone accounts for 20% of the overall decline in the labor force participation for this group from 2014-16, and 25% of the decline in labor force participation among women.

184. Further, people who are addicted to prescription opioid painkillers are 40 times more likely to be addicted to heroin. The CDC identified addiction to prescription pain medication as the strongest risk factor for heroin addiction. Nationally, roughly 80% of heroin users previously used prescription opioids. Studies have shown that heroin use is 19-times greater among individuals who reported past use of prescription pain relievers.

185. Law enforcement, likewise, has both shouldered and witnessed the costs of opioid abuse. In 2016, there were nearly 550 arrests in Puerto Rico for opioid possession and nearly 15,000 pills gathered as evidence from arrests. Further, in 2016 the Puerto Rico Police Department reported finding an additional 10,034 opioid pills unrelated to arrests.

186. According to a survey conducted at schools across Puerto Rico, as many as 8.6% of children ages 12-17 are using prescription pills, including opioids, to get high.

187. Even infants have been impacted by opioids due to suffering from neonatal abstinence syndrome ("NAS"). The average hospital stay for a baby with NAS is 30 days, with an average charge to the Puerto Rico's public health insurance program of $1,000 per day. Additionally, hospitals in Puerto Rico do not have the proper medications needed to treat NAS, therefore hospitals must order the medications from the U.S. mainland, and often bear the higher costs of doing so.

188. According to the CDC, Hepatitis C ("HCV") is largely contracted through the sharing of needles during injection drug use. A recent study conducted by the University of Nebraska found that approximately 90% of people who inject drugs in Puerto Rico are infected with HCV. Addiction treatment providers in Puerto Rico confirm these numbers, reporting that many of their patients have HCV. A treatment course for HCV can cost roughly $80,000.

189. The opioid crisis has also impacted HIV rates within Puerto Rico. Puerto Rico has the fourth highest rate of HIV in the United States, and 33.8 per 100,000 persons are HIV positive, as compared to the national average of 19.7 persons. Nearly half the men who are HIV positive in Puerto Rico contracted the virus through drug injection.

190. Hurricane María also created special challenges for Puerto Rico residents who sought treatment. Several addiction treatment centers closed because they were damaged, destroyed or lacked running water and electricity. Because of this, many residents who were in treatment programs prior to the hurricane returned to using opioids, which has further escalated the opioid crisis within Puerto Rico.

191. A recent, even more deadly problem stemming from the prescription opioid epidemic

involves fentanyl—a powerful opioid prescribed for cancer pain or in hospital settings that, in synthetic form, has made its way into Puerto Rico, like elsewhere. According to an assessment to target the opioid crisis conducted by the Government of Puerto Rico, fentanyl is becoming an alarming trend in Puerto Rico, and treatment providers reported that most drug tests administered test positive for fentanyl.

192. As a result of the impacts described above, the Government has taken significant measures to combat the public health crisis created by the oversupply of opioids. One such recent effort includes the passing of Law 70 of 2017, which orders the development of programs and education on controlled prescription substances and creates an electronic system that monitors prescriptions of controlled substances. Puerto Rico's public health insurance program, Mi Salud, covers approximately 45% of Puerto Rico's residents and reported that in 2016 there were 1,314 claims of emergency room visits for opioid intoxication. Mi Salud spent nearly $4 million on opioid claims in 2012, and this number increased to over $6 million in 2013. In 2014, this number increased again—to over $9 million.

193. Further, in order to curb the opioid crisis, the Department of Mental Health and Substance Abuse recently created six methadone clinics, four methadone medication centers, and four mobile units. Through these clinics and centers, the Department served over 4,000 residents in 2016. In 2015, Puerto Rico spent over $4 million on these programs alone. In addition to the methadone clinics, centers, and mobile units, the Department spends millions of dollars each year to pay for drug court, "Treatment Alternative to Street Crime (Programa TASC)," a drug diversion program for those charged with non-violent drug crimes, and a community outreach program. Each of these programs was created in order to address the opioid epidemic in Puerto Rico.

194. The Puerto Rico Emergency Medical Services, known in Puerto Rico as Cuerpo de Emergencias Médicas ("CEM"), has devoted significant resources to dealing with the opioid crisis.

In 2017, CEM responded to a total of 612 drug-related overdose calls, including many calls related to opioids. Beginning January 1, 2018 until March 19, 2018, CEM responded to 147 drug-related overdose calls, an average of nearly 2 calls per day.

195. While the Department of Justice's investigation has found significant evidence both of Defendants' misconduct and the harm that Defendants have caused in and to Puerto Rico, Puerto Rico's ability to gather information to demonstrate the impact of the opioid crisis on its already strained resources and its residents has been impacted by Hurricane Maria and COVID-19. Government employees continue to focus on relief efforts and some records cannot be easily obtained in the hurricane's aftermath and due to COVID restrictions. In addition, hospitals continue to struggle with damaged infrastructure and many addiction treatment programs that operated prior to the hurricane have not reopened their doors. While the Secretary of the Department of Justice continues to work to gather information, under the circumstances, it will need to rely on discovery to fill in gaps in its own data.

(D) DEFENDANTS FRAUDULENTLY CONCEALED THEIR MISCONDUCT

196. Defendants also fraudulently concealed their misconduct. They declined to release the ARCOS data which provides detailed tracking information about their shipments. In addition, as explained above, Defendants publicly portray themselves as maintaining sophisticated technology as part of a concerted effort to thwart diversion and publicly portrays themselves as committed to fighting the opioid epidemic. Their public pronouncements, however, are at odds with their concealed misconduct. On February 26, 2018, Judge Dan A. Polster, who presides over the Multidistrict Opioid Litigation, ordered that the Drug Enforcement Administration release ARCOS data reflecting the market share of various manufacturers, distributors, and dispensers in the states and Puerto Rico.

197. To the extent that information about Defendants' violations of the federal CSA and its implementing regulations was disclosed through settlement agreements, that information concerned facilities outside Puerto Rico, but such enforcement actions are relevant to Defendants' conduct in Puerto Rico and throughout the country. Further, as described in this Complaint, such settlement agreements have typically been followed by or coupled with promises to improve compliance.

198. Defendants were deliberate in taking steps to conceal their active role in the oversupply of opioids and their failure to prevent the entry of prescription drugs into illicit markets, which fueled the opioid epidemic.

199. As set forth in this Complaint, Defendants concealed the existence of the Government's claims by hiding their lack of cooperation with law enforcement and affirmatively seeking to convince the public that their legal duties to report suspicious orders and maintain effective controls against diversion had been satisfied through public assurances that they were working to curb the opioid epidemic. Defendants publicly portrayed themselves as committed to working diligently with law enforcement and others to prevent diversion of these dangerous drugs and curb the opioid epidemic, and they made broad promises to change their ways, insisting they were good corporate citizens. These repeated misrepresentations misled regulators, prescribers and the public, including the Government of Puerto Rico, and deprived Puerto Rico of actual or implied knowledge of facts sufficient to put it on notice of potential claims.

200. The Government of Puerto Rico did not discover the nature, scope, and magnitude of Defendants' misconduct and its full impact on Puerto Rico until recently, and Puerto Rico could not have acquired such knowledge earlier through the exercise of reasonable diligence.

IV. CAUSES OF ACTION

COUNT 1: PUBLIC NUISANCE

201. Puerto Rico incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

202. A public nuisance includes a condition dangerous to health and is codified under 32 L.P.R.A. § 2761 and 32 L.P.R.A. § 3532.

203. Defendants' conduct, as described in the Complaint, involves the illegal sale of controlled substances. Defendants' conduct has created an ongoing, significant, unlawful, and unreasonable interference with rights common to the general public, including the public health, welfare, safety, peace, comfort, and convenience of the Government and its communities. *See* Restatement (Second) of Torts § 821B.

204. The interference is unreasonable because Defendants' nuisance-creating conduct:

a. Involves a significant interference with the public health, the public safety, the public peace, the public comfort, and/or the public convenience;
b. At all relevant times was and is proscribed by state and federal laws and regulations; and/or
c. Is of a continuing nature and, as Defendants know, have had and are continuing to have a significant effect upon rights common to the general public, including the public health, the public safety, the public peace, the public comfort, and/or the public convenience.

205. The significant interference with rights common to the general public is described in detail throughout this Complaint and includes:

a. The creation and fostering of an illegal, secondary market for prescription opioids;
b. Easy access to prescription opioids by children and teenagers;
c. A staggering increase in opioid abuse, addiction, overdose, injuries, and deaths;

d. Infants being born dependent on opioids due to prenatal exposure, causing severe withdrawal symptoms and lasting developmental impacts;
e. Employers have lost the value of productive and healthy employees; and
f. Increased costs and expenses for the Government relating to healthcare services, law enforcement, the criminal justice system, social services, and education systems.

206. Additionally, Defendants' failure to design and operate a system that would disclose the existence of suspicious orders of controlled substances, its failure to report suspicious orders to DEA, and its failure to reject suspicious orders of opioids violated the Puerto Rico Controlled Substance Act, 24 L.P.R.A. § 2303 (b)(1),(2) (which also incorporates the CSA's obligations) and the CSA, 21 C.F.R. §1301.74(b), which require registrants to maintain effective controls against diversion.

207. Defendants' unlawful nuisance-creating conduct includes violating federal and Puerto Rico statutes and regulations, including the controlled substances laws, by:

a. Selling opioids in ways that facilitated and encouraged their flow into the illegal, secondary market;
b. Selling opioids without maintaining effective controls against the diversion of opioids;
c. Choosing not to effectively monitor for suspicious orders;
d. Choosing not to investigate suspicious orders;
e. Choosing not to report suspicious orders;
f. Choosing not to stop or suspend shipments of suspicious orders;
g. Selling opioids prescribed by "pill mills" when Defendants knew or should have known the opioids were being prescribed by "pill mills."

208. Defendants' intentional and unreasonable nuisance-creating conduct, for which the gravity of the harm outweighs the utility of the conduct, includes:

a. Selling opioids in ways that facilitated and encouraged their flow into the illegal, secondary market;
b. Selling opioids without maintaining effective controls against the diversion of opioids;
c. Choosing not to effectively monitor for suspicious orders;
d. Choosing not to investigate suspicious orders;
e. Choosing not to report suspicious orders;
f. Choosing not to stop or suspend shipments of suspicious orders;
g. Selling opioids prescribed by "pill mills" when Defendants knew or should have known the opioids were being prescribed by "pill mills;" and
h. Misrepresenting the risks of Actiq and Fentora to formularies.

209. Defendants intentionally and unreasonably sold opioids that Defendants knew would be diverted into the illegal, secondary market and would be obtained by persons with criminal purposes.

210. In light of Defendants' failures to disclose suspicious orders of opioids, failure to halt suspicious orders, failure to effectively monitor for suspicious orders, and failure to maintain adequate controls to prevent diversion, Puerto Rico was unaware of, and could not reasonably know or have learned through reasonable diligence, that it had been exposed to the risks alleged herein. Information pertaining to the suspicious orders of opioids Defendants were required to disclose—but did not—was information that Defendants, given their placement in the supply chain, are uniquely positioned to possess and which was otherwise unavailable Puerto Rico. At all times relevant to this Complaint, Defendants were in complete control over the instrumentalities constituting the public nuisance.

211. Defendants' actions were, at the very least, a substantial factor in opioids becoming widely available and widely used in Puerto Rico. By failing to report and failing to exercise due diligence not to fill suspicious orders in Puerto Rico, and by failing to implement policies and

procedures to guard against diversion, Defendants exacerbated the opioid crisis in Puerto Rico and failed to limit its reach. Defendants controlled these actions and, therefore, willingly participated to a substantial extent in creating and maintaining the public nuisance. Without Defendants' actions, opioid use, misuse, abuse, and addiction would not have become so widespread, and the opioid epidemic that now exists would have been averted or much less severe.

212. Defendants' conduct is unreasonable, intentional, and unlawful.

213. Defendants knew of the public health hazard their conduct would create.

214. Defendants intentionally, recklessly, or negligently engaged in conduct proscribed by statute, ordinance or administrative regulation, as described in this Complaint, including a breach of duty to exercise reasonable care under the Puerto Rico Controlled Substances Act, 24 L.P.R.A. §2303(b), and the Fair Competition Act, 10 L.P.R.A. § 259, which require that registrants satisfy registration and licensing requirements mandating that they maintain an "effective control against the diversion of particular controlled substances and any controlled substance in Schedule I or II compounded therefrom into other than legitimate medical, scientific, or industrial channels" and comply with "applicable federal and local law," including the mandates of the federal Controlled Substances Act set forth in 21 U.S.C. § 823 and 21 C.F.R. 1301.74. and the Puerto Rico Controlled Substances Act, 24 L.P.R.A. § 2303(b).

215. The public nuisance is substantial and unreasonable. Defendants' actions caused and continue to cause the public health epidemic and state of emergency described in this Complaint.

216. Defendants had control over their acts and omissions, the instrumentalities causing the public nuisance, at the time the nuisance occurred. Defendants had control over their own shipments of opioids and over their reporting, or lack thereof, of suspicious prescribers and orders. Defendants controlled the systems they developed to control against diversion, including the

criteria and process used to identify red flags of suspicious orders or prescribing.

217. Defendants' conduct directly and proximately caused injury to Puerto Rico and its residents.

218. The public nuisance created, perpetuated, and maintained by Defendants, and further recurrence of such harm and inconvenience can be abated by (a) educating prescribers (especially primary care physicians and the most prolific prescribers) and patients regarding the true risks and benefits of opioids, including the risk of addiction, in order to prevent the next cycle of addiction; (b) providing addiction treatment to patients who are already addicted to opioids; (c) retrieving and disposing of excess opioids, eliminating a primary pathway of exposure for adolescents; (d) providing screening and treatment to pregnant women and newborns to reduce the incidence and impact of prenatal exposure; (e) making naloxone widely available so that overdoses are less frequently fatal; and (f) restraining the channels for diverting opioids by appropriately setting and enforcing customer limits, reporting suspicious orders, prescribers, and customers, and stopping, rather than simply delaying, the shipment of suspicious orders, among other measures.

219. Defendants have the ability to act to abate the public nuisance, and in certain respects, the law recognizes that they are uniquely well positioned to do so. Defendants are also uniquely able to stop fueling, and to cut off at the source, diversion of prescription opioids. As a registered manufacturer of controlled substances, Defendants are placed in a position of special trust and responsibility.

WHEREFORE, Puerto Rico respectfully requests that this Court enter an order awarding judgment in its favor and against Defendants on Count One of the Complaint; for Defendants to abate and pay damages for the public nuisance; and for an injunction permanently enjoining Defendants from engaging in the acts and practices that caused the public nuisance, pursuant to 32

L.P.R.A. § 3532.

COUNT II: NEGLIGENCE/FAULT

220. Puerto Rico incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

221. Pursuant to 31 L.P.R.A. § 5141, a "person who by an act or omission causes damage to another through fault or negligence shall be obliged to repair the damage so done."

222. Defendants have a duty to exercise reasonable care in selling highly dangerous opioid drugs in Puerto Rico.

223. Defendants have an affirmative duty to exercise reasonable care under the circumstances, in light of the risks. This includes a duty not to cause foreseeable harm to others.

224. As manufacturers, Defendants had distinct reporting requirements regarding suspicious orders of opioids.

225. In addition, Defendants, having engaged in a course of conduct that created a foreseeable risk of injury, had, and still have, a duty to protect others from such injury. Like every person, Defendants owe a duty of ordinary care to all others to guard against injuries which naturally flow as a reasonably probable and foreseeable consequences of their actions.

226. Defendants are part of a limited class of registrants authorized to legally sell controlled substances, which places them in a position of great trust and responsibility vis a vis Puerto Rico. Their duty cannot be delegated.

227. In addition, 21 U.S.C. § 801 *et seq.*; 21 C.F.R. § 1301.74; 21 C.F.R. § 205; the PRCSA, including 24 L.P.R.A. § 2303 (b), are public safety laws. Each Defendant had a duty under, *inter alia*, 21 U.S.C. § 801 *et seq.*, 21 C.F.R. § 1301.74, and 24 L.P.R.A. § 2303 (b)(1-2), to maintain effective controls against diversion of prescription opioids, to report suspicious orders of opioids,

and not to fill suspicious orders unless and until due diligence had eliminated the basis for their suspicion.

228. Defendants also misleadingly portrayed themselves as cooperating with law enforcement and actively working to combat the opioid epidemic when, in reality, Defendants failed to satisfy even their minimum, legally-required obligations to report suspicious prescribers and orders. Defendants voluntarily undertook duties, through their statements to the media, regulators, and the public at large, to take all reasonable precautions to prevent drug diversion.

229. Upon information and belief, Defendants repeatedly and recklessly or intentionally breached their duties. These breaches included:

a. Selling prescription opioids in the supply chain when they knew, or should have known, that there was a substantial likelihood the sale was for non-medical purposes and that opioids are an inherently dangerous product when used for non-medical purposes;
b. Using unsafe sales practices;
c. Inviting criminal activity into Puerto Rico by disregarding precautionary measures built into the CSA, PRCSA, and these statutes' implementing regulations;
d. Failing to comply with the public safety laws described above;
e. Failing to acquire or utilize special knowledge or skills that relate to the dangerous activity of selling opioids in order to prevent or ameliorate such significant dangers;
f. Failing to review prescription orders for red flags;
g. Failing to report suspicious orders or refuse to fill them;
h. Permitting prescriptions to be filled where red flag warnings indicated potential diversion.
i. Failing to provide effective controls and procedures to guard against theft and diversion of controlled substances;
j. Failing to exercise due diligence to ensure that customers could be trusted with opioids; and
k. Misrepresenting the risks of Actiq and Fentora to formularies.

230. Defendants breached their duty to exercise the degree of care, prudence, watchfulness, and vigilance commensurate with the dangers involved in selling dangerous controlled substances.

231. Defendants acted with actual malice in breaching their duties, *i.e.*, they have acted with a conscious disregard for the rights and safety of other persons, and said actions have a great probability of causing substantial harm.

232. The foreseeable harm from a breach of these duties is the sale, use, abuse, and diversion of prescription opioids.

233. The foreseeable harm from a breach of these duties also includes abuse, addiction, morbidity and mortality in Puerto Rico.

234. Reasonably prudent manufacturers of prescription opioids would have anticipated that the scourge of opioid addiction would wreak havoc on communities, and the significant costs which would be imposed upon the governmental entities associated with those communities. The closed system of opioid sales exists for the purpose of controlling dangerous substances such as opioids and preventing diversion and abuse to prevent precisely these types of harms. The very purpose of these duties was to prevent the diversion of highly addictive drugs for non-medical purposes and the resulting harm.

235. Reasonably prudent manufacturers would know that failing to report suspicious orders would lead to diversion of the opioids they shipped. Reasonably prudent manufacturers would also know that filling such orders without first exercising due diligence would create an environment in which diversion would occur.

236. Puerto Rico seeks recovery for its economic losses (direct, incidental, or consequential pecuniary losses) resulting from Defendants' negligence, pursuant to 31 L.P.R.A. §5141. Puerto Rico does not seek damages for the wrongful death, physical personal injury, serious emotional

distress, or any physical damage to property caused by Defendants' actions.

237. Defendants' breach of the duties described in this Count directly and proximately resulted in the injuries and damages alleged by Puerto Rico.

238. The misconduct alleged in this case is ongoing and persistent.

239. The misconduct alleged in this case does not concern a discrete event or discrete emergency of the sort the Government would reasonably expect to occur, and is not part of the normal and expected costs of its existence. The Government alleges wrongful acts which are neither discrete nor of the sort it can reasonably expect.

240. Puerto Rico has incurred expenditures for special programs over and above the Government's ordinary services.

WHEREFORE, Puerto Rico respectfully requests that this Court enter an order awarding judgment in its favor and against Defendants on Count II of the Complaint, pursuant to 31 L.P.R.A § 5141.

COUNT III: FAIR COMPETITION ACT

241. Puerto Rico incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

242. At all times relevant to this Complaint, Defendants violated the Fair Competition Act as codified in 10 L.P.R.A. § 259 by engaging in unfair acts or practices in selling opioids in Puerto Rico. These acts or practices are unfair in that they offend public policy; are immoral, unethical, oppressive, or unscrupulous; and have resulted in substantial injury to Puerto Rico consumers that is not outweighed by any countervailing benefits to consumers or competition.

243. Defendants' unfair acts or practices include, but are not limited to failing to maintain effective controls against opioid diversion, in violation of 24 L.P.R.A. § 2303 (b)(1) and 24

L.P.R.A. § 2303 (b)(2) by:

a. Failing to create and maintain and use a compliance program that effectively detects and prevents suspicious orders of controlled substances;
b. Failing to report suspicious orders of controlled substances;
c. Filling suspicious or invalid orders for prescription opioids;
d. Permitting orders to be filled where red flag warnings indicated potential diversion;
e. Failing to exercise due diligence to ensure that customers could be trusted with opioids; and
f. Misrepresenting the risks of Actiq and Fentora to formularies.

244. Defendants engaged in further misrepresentations in violation of 10 L.P.R.A. § 259 by publicly claiming to use advanced analytics and technology to address suspicious orders and prevent illegitimate use of prescription opioids while actually failing to maintain effective controls against diversion. Defendants' misrepresentations regarding their use of advanced analytics are deceptive acts under 10 L.P.R.A. § 259.

245. Defendants engaged in further deception in violation of 10 L.P.R.A. § 259 through their registration with the Puerto Rico Secretary of Health by affirming that they would maintain adequate controls to prevent diversion of their opioids pursuant to 24 L.P.R.A. §2303(b). Defendants failed to maintain effective controls, however, which created widespread diversion throughout Puerto Rico. Defendants' misrepresentations that they would maintain adequate controls were unlawful pursuant to 10 L.P.R.A. § 259.

246. Defendants' practices as described above offend deep-seated public policies, as the Puerto Rico legislature recognized in enacting the Puerto Rico Controlled Substances Act, the recently-signed Law 70-2017, and the creation of several methadone clinics and medication centers. Nevertheless, by engaging in the conduct alleged above, Defendants profited from the opioid epidemic in Puerto Rico by turning a blind eye to orders that Defendants knew or should have

known were likely to be diverted.

247. Defendants' conduct has caused substantial, indeed grievous, injury to Puerto Rico—in lives lost to drug overdoses; addictions endured; emergency room visits; the creation of an illicit drug market and all its concomitant crime and costs; unrealized economic productivity; and broken lives, families, and homes.

248. The profound injuries to Puerto Rico consumers are not outweighed by any countervailing benefits to consumers or competition since there is no benefit from oversupplying of opioids to Puerto Rico. In light of Defendants' lack of transparency and public claims of commitment to exercising due diligence not to fuel abuse and diversion of prescription opioids, Puerto Rico consumers could not reasonably have avoided their injuries.

249. By reason of Defendants' unlawful acts, Puerto Rico consumers and Puerto Rico have been damaged, and continue to be damaged, in a substantial amount to be determined at trial.

250. The misconduct alleged in this case does not concern a discrete event or discrete emergency of the sort the Government would reasonably expect to occur, and is not part of the normal and expected costs of Government existence. Puerto Rico alleges wrongful acts which are neither discrete nor of the sort that the Government can reasonably expect.

251. Puerto Rico has incurred expenditures for special programs over and above Puerto Rico's services.

252. Upon information and belief, based on the pervasive pattern and practice of Defendants' conduct, Defendants' directors, officers, managers, trustees, and agents authorized, ordered and as a result of Defendants' conduct as alleged herein, injured Puerto Rico consumers including the Government and its agencies, suffered and continue to suffer injury.

WHEREFORE, Puerto Rico, respectfully requests that this Court enter an order awarding

judgment in its favor and against the Defendants on Count III of the Complaint.

COUNT IV: UNJUST ENRICHMENT

253. The Government incorporates the preceding paragraphs as if fully set forth herein.

254. Defendants have unjustly retained a benefit to Puerto Rico's detriment, and Defendants' retention of that benefit violates the fundamental principles of justice, equity, and good conscience.

255. As an expected and intended result of their conscious wrongdoing as set forth in this Complaint, Defendants have profited and benefited from the increase in the sale of opioids within Puerto Rico.

256. Puerto Rico has expended substantial amounts of money in an effort to remedy or mitigate the societal harms caused by Defendants' conduct.

257. These expenditures include the provision of healthcare services and treatment services to people who use opioids.

258. These expenditures have helped sustain Defendants' businesses.

259. Puerto Rico has conferred a benefit upon Defendants by paying for their externalities: the cost of the harms caused by Defendants' improper sales practices.

260. Puerto Rico has also conferred a benefit upon Defendants by paying for purchases by unauthorized users of prescription opioids from the Defendants' supply chain for non-medical purposes.

261. Puerto Rico has paid for the cost of Defendants' externalities, and Defendants have benefited from those payments, because they allowed Defendants to manufacture, market, and sell more of their opioid products. Because of their conscious failure to exercise due diligence in preventing diversion, Defendants obtained enrichment they would not otherwise have obtained. The enrichment was without justification and Plaintiff's lack a remedy provided by law.

262. Accordingly, under principles of equity, Defendants should be disgorged of money retained by reason of their deceptive and illegal acts that in equity and good conscience belong to Puerto Rico and its residents.

V. PRAYER FOR RELIEF

263. WHEREFORE, the Government prays for judgment against Defendants as permitted by Puerto Rico law, as follows:

264. For a declaration that Defendants have violated the Fair Competition Act;

265. For an injunction pursuant to 10 L.P.R.A. §269 enjoining Defendants from engaging in any acts that violate the Fair Competition Act, including, but not limited to, the unfair and deceptive acts and practices, and unfair methods of competition alleged in this Complaint;

266. For further remedies as deemed as appropriate pursuant to 10 L.P.R.A §269 for engaging in any acts that violate the Fair Competition Act.

267. For civil penalties against Defendants and their directors, officers, managers, trustees and agents in the amount of $25,000 for each and every violation of the Fair Competition Act under 10 L.P.R.A. § 265;

268. For damages suffered for each violation of 10 L.P.R.A. §268;

269. For an injunction permanently enjoining Defendants from engaging the acts and practices that caused the public nuisance pursuant to 32 L.P.R.A. § 3532;

270. For an order directing Defendants to abate and pay damages for the public nuisance;

271. For damages for Defendants' fault and negligence pursuant to 31 L.P.R.A. §5141;

272. For restitution or disgorgement of Defendants' unjust enrichment, benefits, and ill-gotten gains, plus interest, acquired as a result of the unlawful or wrongful conduct alleged herein;

273. For costs, interest, and attorney's fees; and

274. For all other relief permitted by 31 L.P.R.A. § 7 and such further relief deemed just by the Court.

RESPECTFULLY SUBMITTED.

In San Juan, Puerto Rico, this 27th day of August 2021.

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VERIFICATION

Pursuant to 32 L.P.R.A § 3532, I declare as follows:

1. I have read the factual allegations regarding public nuisance in the foregoing Complaint and believe they are well-grounded in fact;

2. The allegations of public nuisance are true to my personal knowledge, except as they may be stated upon information and belief;

3. As to those matters alleged upon information and belief in regards to public nuisance, I have made reasonable inquiry of the facts of such matters and have adequate information to form a reasonable belief as to their truths;

4. The Complaint is warranted by existing law, or a good faith argument for the extension modification or reversal of existing law; and

5. The Complaint has not been made for any improper purpose, including to harass, to cause unnecessary delay, to force a needless increase in the cost of litigation, or to force an unjust settlement through the serious nature of the averment.

6. Pursuant to 32 L.P.R.A. § 3532, I declare under the penalty of perjury that foregoing is true and correct.

Executed in San Juan, Puerto Rico this 27 day of August, 2021.

HON. DOMINGO EMANUELLI
SECRETARIO DE JUSTICIA
DEPARTAMENTO DE JUSTICIA
GOBIERNO DE PUERTO RICO

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